

November 26, 2003

Dear Colleagues:

The attached *Procedural Guidance* accompanies the CDC Program Announcement, HIV Prevention Projects for Community-Based Organizations (Funding Opportunity Number 04064), as Attachment I. To receive funding under Program Announcement #04064, organizations must propose in their applications to implement interventions from the *Procedural Guidance* appropriate for their respective target populations and their organization's capacity to conduct them. The *Procedural Guidance* was developed to bring the best available science on HIV prevention to inform organizations that are considering applying for funding to implement HIV prevention in their communities. Interventions that are not in the *Procedural Guidance* will not be funded. CDC will provide training to organizations selected for funding on the implementation of specific interventions and also offer capacity building technical assistance throughout the duration of the project period.

Although CDC recognizes the empirical contributions of programs that have not undergone rigorous evaluation, the redoubling of prevention efforts requires that we support programs with evidence of effectiveness for reducing behaviors associated with the transmission of HIV. Through a thorough review of the literature on HIV prevention interventions, and with contributions from researchers and program experts, this *Guidance* brings consistency to, and support for, the delivery of evidence-based HIV prevention interventions and strategies.

The *Guidance* is divided into 3 sections, which match the 3 major activities that will be funded through Program Announcement #04064. Section 1 describes procedures for targeted outreach and health education/risk reduction (HE/RR) for high-risk individuals. Section 2 describes procedures for targeted outreach and counseling, testing, and referral (CTR) services for high-risk individuals. Section 3 describes procedures for prevention interventions for people living with HIV and their partners of negative or unknown serostatus. Section 3 also includes interventions for persons at very high risk for HIV infection, defined as someone who, within the past 6 months, has had unprotected sex with a person who is living with HIV; unprotected sex in exchange for money or sex; multiple (greater than 5) or anonymous unprotected sex or needle-sharing partners; or has been diagnosed with a sexually transmitted disease.

This *Guidance*, along with intervention kits produced by the Replicating Effective Programs (REP) project and those disseminated by the Diffusion of Effective Behavioral Interventions (DEBI) project represent the best currently available science related to HIV prevention. This document is a DRAFT and CDC will be updating the *Procedural Guidance* with more specific procedures for some of the interventions next week. To address questions or comments about the *Procedural Guidance* document, a toll-free telephone number (1-866-329-2669) has been established and will be active through February 13, 2004. Questions about the procedures after February 13th can be directed to CDC project officers. This document represents a work in progress and we welcome your comments and suggestions.

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PROCEDURAL GUIDANCE FOR SELECTED
STRATEGIES AND INTERVENTIONS FOR
COMMUNITY BASED ORGANIZATIONS
FUNDED UNDER PROGRAM
ANNOUNCEMENT 04064

Draft 9 Dec 03

Acknowledgements

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PROCEDURAL GUIDANCE FOR SELECTED STRATEGIES AND INTERVENTIONS FOR COMMUNITY BASED ORGANIZATIONS FUNDED UNDER PROGRAM ANNOUNCEMENT 04064

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Since the early days of the HIV/AIDS epidemic the Centers for Disease Control and Prevention (CDC) has worked with its partners to prevent the acquisition and transmission of HIV. Through the tireless work of dedicated frontline staff, medical professionals, and researchers, a number of successes have been realized. Behavioral interventions and medical advances have led to improvements in survival and quality of life for many people living with HIV and to decreases in the number of new infections. However, after years of declining infection rates, the number of new infections began to stabilize at about 40,000 per year in the early 1990's. Two concerning trends have emerged recently. First, data indicate that there has been an increase in behaviors that put people at risk of infection with HIV. Second, syphilis cases increased for the second year in 2002, reversing a decade of decline. In addition, trends in HIV diagnoses in 25 states with HIV reporting since 1993 show a rise for the first time in over a decade. It remains to be seen if this trend is due to increased testing or to an increase in the number of new infections. In the third decade of the epidemic, the HIV/AIDS prevention community is facing increasing challenges to which we must respond.

The purpose of the *Guidance* is to provide community-based organizations (CBOs) with sufficient information about the services described in order to determine activities for which they will request funding under Program Announcement 04064. To receive funding under CDC's Program Announcement 04064, organizations must propose in their applications to implement interventions from the *Guidance* appropriate for their respective target populations and their organization's capacity to conduct them. Interventions that are not in the *Guidance* will not be funded.

The information contained in this document should assist agencies in creating a plan for delivery of the service. It is not intended to provide the level of operational detail necessary to fully design and implement the programs described. CDC will provide intervention materials, and

training and technical assistance related to the interventions and services described in this *Guidance* to ensure that successful applicants understanding of the appropriate procedures for delivery and monitoring of the services to be provided. Many of these materials are already available (www.effectiveinterventions.org) and others will be available in the coming months.

In April 2003, CDC announced a refocusing of its prevention efforts to meet these challenges. *Advancing HIV Prevention: New Strategies for a Changing Epidemic* aims to support the prevention work of the past two decades while using emerging technologies (e.g., rapid testing, new interventions designed to meet the prevention needs of people living with HIV (PLWH) to expand and strengthen our efforts. The strategies identified to help achieve this goal focus directly on reducing barriers to early diagnosis; improving referral to state-of-the-art preventions services, medical care, and treatment; and ensuring that prevention programs are in place to assist people living with HIV. This *Guidance* provides direction for the design of community-based programs that address the strategies of AHP and meet the needs of communities.

In Program Announcement 04064, CDC will continue to support interventions for people at high risk for HIV infections and will also fund interventions in support of AHP.

The Procedural Guidance

The *Procedural Guidance* was developed as a means of bringing the best available science on HIV prevention to organizations that are working to meet the prevention needs of their communities. Although CDC recognizes the contribution of programs that have not yet received rigorous evaluation, the redoubling of prevention efforts has led to the need to place a premium on programs with evidence of effectiveness for reducing behaviors associated with the transmission of HIV. Through a thorough review of the literature on HIV prevention interventions, and with contributions from researchers and program experts, this *Guidance* is presented as a means to bring consistency to, and support for, the delivery of evidence-based HIV prevention interventions and strategies.

The *Guidance* is divided into 3 sections, which match the 3 major activities that will be funded through Program Announcement #04064. Section 1 describes procedures for targeted outreach and health education/risk reduction (HE/RR) for high-risk individuals. Section 2 describes procedures for targeted outreach and counseling, testing, and referral (CTR) services for high-risk individuals. Section 3 describes procedures for prevention interventions for people living with HIV and their partners of negative or unknown serostatus. Section 3 also includes interventions for persons at very high risk for HIV infection, defined as someone who, within the past 6 months, has had unprotected sex with a person who is living with HIV; unprotected sex in exchange for money or sex; multiple (greater than 5) or anonymous unprotected sex or needle-sharing partners; or has been diagnosed with a sexually transmitted disease.

This *Guidance*, along with intervention kits produced by the Replicating Effective Programs (REP) project and disseminated by the Diffusion of Effective Behavioral Interventions (DEBI) project represent the best currently available science related to HIV prevention.

The REP project translates HIV prevention interventions that have been shown to be effective at reducing risk behaviors into everyday language and puts them into user-friendly packages of

materials. REP interventions are available on the web at <http://www.cdc.gov/hiv/projects/rep/default.htm>.

The DEBI project is a national-level strategy to provide training and on-going technical assistance on selected evidence-based HIV/STD interventions to state and community program staff. DEBI interventions are available on the web at <http://www.effectiveinterventions.org>.

These evidence-based interventions will be supported by CDC, and organizations interested in partnering with CDC can choose from these interventions to create a plan for services that will meet the needs of their clients.

Not all agencies will have the capacity to deliver the interventions and services as they are described in this *Guidance*. Those agencies that are interested in a particular strategy but are unable to address all aspects of that service should partner with complementary agencies that would bring additional skills to the collaboration.

How to use the *Guidance*

The *Procedural Guidance* provides direction for the design of prevention programs including recruitment strategies to promote counseling and testing, HE/RR, and other prevention services; counseling, testing and referral (CTR) strategies; and prevention interventions to meet the needs of PLWH, their partners, and other uninfected individuals at high risk for HIV. Each strategy or intervention is outlined using the following eight subheadings:

Description: Provides a brief description of the strategy and evidence of effectiveness.

Core Elements, Key Characteristics, and Procedures:

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy.

Procedures describe the activities that make up the content of the program and provide direction to agencies or organizations regarding its implementation.

These features will be elaborated below in the description of adaptation and tailoring of interventions.

Resource Requirements: Discusses the ideal staffing patterns and materials needed for effective implementation of the intervention

Recruitment: Gives guidance on the recruitment activities that have been successful for the strategy or intervention described, and/or refers the reader to choose a strategy from the *Procedural Guidance for Recruitment* (included in this document) that is most appropriate for the organization or population.

Physical Setting and Characteristics: Describes the ideal setting or location for implementing the strategy or intervention described.

Necessary Policies and Standards: Discusses the policies which must be in place within an agency or organization to implement an intervention or strategy with respect to legal, ethical, and culturally appropriate guidelines.

Quality Assurance: Provides procedures for ensuring that the intervention or strategy is carried out with fidelity and with respect to the necessary policies and standards.

Monitoring and Evaluation: Describes data to be collected to ensure that the intervention or strategy is reaching the intended population and to determine effectiveness.

Adaptation and Tailoring

Interventions to prevent the acquisition of HIV (interventions directed toward people of negative or unknown serostatus) have received a great deal of attention from researchers and others interested in HIV prevention since transmission routes were identified in the early years of the epidemic. For this reason, the number of evidence-based interventions for this group has grown steadily, and interventions are now available for a variety of populations and settings. Interventions to reach individuals of negative or unknown HIV status at high risk for HIV infection can be found on the REP and DEBI websites listed above. As PLWH have been diagnosed earlier in their infection, and treatment advances have led to greater length and quality of life, the prevention needs of PLWH have begun to receive more attention. Currently, a number of science-based interventions are available to address the strategies of the AHP initiative. The need for additional, proven prevention-with-positive interventions is being addressed by the scientific community, with several interventions currently being evaluated.

While the investigators who designed these interventions have made every attempt in their research efforts to include the groups that are most impacted by the HIV/AIDS epidemic, no intervention study can be designed to demonstrate efficacy in every group at risk for transmission or acquisition of HIV. However, because the theories of behavior change upon which interventions are based are generalizable across a number of behaviors and populations, the interventions can be adapted and tailored to meet the specific needs of groups that were not part of the original research. While the core elements of an intervention cannot be changed, the key characteristics can be modified to suit the needs of the agency or target population.

Adaptation of an intervention or strategy implies that it is being delivered to a different population or in a different venue than the one in which efficacy was originally demonstrated. For example, the Popular Opinion Leader intervention was originally designed to reach gay men in bars, but was successfully adapted for use with African-American women in an urban housing

project. VOICES/VOCES was originally tested in sexually transmitted disease (STD) clinics but has been found to be appropriate when delivered to persons in drug treatment settings.

Tailoring, on the other hand, occurs when an intervention or strategy is changed to deliver a new message (for example, addressing condom use versus limiting the number of partners), at a new time (at a weekend retreat rather than over a series of weeks), or in a different manner (using verbal rather than written messages) than was originally described.

Adaptation involves changes in *who* receives an intervention and *where* it is delivered, while tailoring leads to changes in *when* it is delivered, *what* is addressed, and *how* the message is conveyed. Adaptation questions should be addressed before attempting to tailor the intervention or service. Adaptation must be addressed before tailoring because the population and the determinants that put persons at risk for HIV infection must be specified before messages and strategies can be tailored to address those risk determinants. In addition, identifying the venues in which the intervention is delivered may assist in determining how the intervention will be delivered. The strategies described in this *Guidance* can be adapted and tailored with a reasonable expectation of success if these variations are based on the demonstrated needs and special circumstances of the population to be addressed.

Adapting or tailoring of an intervention must come from an understanding of the population for which the intervention is intended and should take into account both culturally relevant factors for the group being served as well as thorough knowledge of the risk behaviors and risk determinants that place the population at risk for HIV infection. Providers cannot make the assumption that because an intervention will be delivered by a member of the target population, it will be appropriate for that population. Cultural identity does not necessarily lead to cultural competency. Information about risk behaviors and determinants can only be gathered with an appropriate formative evaluation of the target population.

Formative evaluation is a series of activities undertaken to furnish information that will guide the program adaptation, tailoring, and development process. Formative evaluation involves the identification of the risk determinants that were addressed in an evidence-based intervention and then determining if the new target population has these or similar risk determinants. For example, the SISTA intervention recognizes that African American women must negotiate with their male sexual partners to convince these partners to use condoms. If an organization wanted to adapt SISTA to Hispanic women, they would have to determine if negotiation with male sexual partners was also relevant for Hispanic women. If so, then SISTA may be appropriately adapted for Hispanic women.

Careful review of evidence-based behavioral interventions may also identify important mediators and moderators for achieving the effects of the intervention. *Mediators* are internal facilitators of risk-reduction skill acquisition. Self-efficacy (belief that one can change behavior), intentions (plan to change behavior), perceived peer norms (beliefs about peers' behavior), and outcome expectancy (belief about consequences of behavior change) are often identified as mediators for risk reduction. *Moderators* include external supports and barriers of risk-reduction skill acquisition. For example, Street Smart is an intervention for homeless and runaway adolescents, which is typically delivered in a runaway or homeless shelter. Because the youth are housed in

the shelter, access to the target population has been increased. Thus a moderator, access, has been addressed by taking the intervention to a site where homeless and runaway youth can be reached. When adapting an intervention for a new population it is necessary to determine whether the new target population has the same or similar mediators and moderators influencing risk-reduction behaviors as the original population.

To ensure the best chance of success for an intervention in any community, the needs of that community must be assessed and the goals of the intervention must be specified to ensure that they are in line with the needs and concerns of the target population. Following the steps of a formative evaluation can help an agency or organization to answer adaptation questions regarding to whom an intervention should be delivered, and changes in location that are necessary, as well as tailoring questions such as the most effective message and means of delivery, as well as the timing of the intervention. Steps of a formative evaluation include:

- 1) **Interviews** with community gatekeepers and stakeholders can be used to determine the feasibility of delivering an intervention in the context in which an agency or organization has targeted. Community gatekeepers are persons who can either facilitate or undermine implementation of an intervention in a particular community or venue as well as with a particular target population.

For example, Popular Opinion Leader (POL) an intervention with men who have sex with men (MSM) suggests that owners of gay bars be interviewed prior to implementation of the intervention to ensure that the bar owners endorse the intervention, will allow the intervention to take place in their venue, and will support the intervention by encouraging bar employees to participate in the identification of POLs. Another example is the SISTA intervention, which has been delivered to women in county and city jails. The managers and guards of these facilities must be interviewed prior to implementation to ensure that they will allow the intervention into their facility.

Another consideration is the need to ensure that the service is needed in the opinion of community gatekeepers and stakeholders.

For example, when attempting to adapt and tailor the intervention Safety Counts, community gatekeepers and stakeholders may say “We already have street outreach, why do we need another intervention in our community for drug users?” Agency staff should then explain that Safety Counts is an intervention that actively recruits injection drug and cocaine users into prevention counseling, rapid testing, partner services, individual and group level interventions, prevention case management, medical services and family focused social events. Community gatekeepers and stakeholders must be informed that Safety Counts is a specific outreach method with specific goals and is not the typical outreach they may have experienced in their community in the past.

- 2) These interviews should be followed by **focus groups** of members of the target population to gain an understanding of the issues that are most important to and impact

most strongly upon the community. Before conducting the focus groups, the agency wishing to implement the evidence-based program should design the focus group questions. These questions should elicit information on HIV behavioral risk determinants, mediators for the risk behaviors, and moderators for the risk behaviors. If the risk determinants, mediators, and moderators are similar to those identified in the evidence-based program, then the evidence-based program may be appropriate for adaptation and tailoring. The focus groups must also discuss all the core elements of the original evidence-based intervention.

For example, Mpowerment, an intervention for young gay men, has 5 core elements. These elements are 1) a core group of young gay men who help direct the project, 2) informal outreach to spread safer sex norms, 3) formal outreach to distribute safer sex materials into venues where young gay men can be accessed, 4) M-groups that build social and safer sex skills for young gay men, and 5) social marketing of norms and social events that reach young gay men who may not be reached by other components of the intervention.

Before implementing Mpowerment in a new community, focus groups should be held to determine if each of these core elements of the evidence-based program are feasible and appropriate for the new target population and venues. *Feasibility* includes human and fiscal resources as well as the level of skill attainment agency staff will need to implement the evidence-based intervention. *Appropriate* includes cultural and community values, gender, language, and age-related considerations. Several focus groups may be needed to explore HIV risk determinants in the target population and determine if they match the risk determinants in the evidence-based model. Several more focus groups may be needed to explore each core element of the original evidence-based model intervention to assess the potential of implementing these core elements with a new population or in a new venue.

- 3) The revised intervention should be based upon a **logic model**. The logic model is often displayed in a flow chart or table to portray the sequence of steps leading to expected intervention outcomes. A logic model is a program plan that links an evidence-based problem statement to intervention activities that address the problem statement. These intervention activities must then be linked to measurable intervention outcomes that address the problem statement and demonstrate reduced HIV risk. The logic model should be based on an evidence-based problem statement. The implementing agency should have epidemiological or other evidence that the target population is at risk for HIV infection, should understand the risk determinants for the population, and should document that the problem addressed in the original evidence-based intervention research and the problem in the new target population are similar. The logic model should identify inputs for each core element of the intervention. This means that the implementing agency should identify all the resources necessary to deliver an evidence-based intervention. Resources include human capital (employees, managers, and volunteers), supplies, venue costs, travel costs, incentives, and materials development. These inputs should be calculated for each planned core element. The logic modeling process should

review and consider carefully the behavioral outcomes that were obtained in the original research of the evidence-based intervention. Consideration should be given to the intensity and dosage of intervention activities that must be delivered to ensure that the adapted and tailored program makes every attempt to obtain or surpass the behavioral outcomes that were obtained in the original evidence-based intervention research.

For example, Street Smart was able to increase condom use with homeless and runaway adolescents with 8 intervention sessions. If the implementing agency plans to obtain similar outcomes in their adapted and tailored program, they must be willing and able to provide a similar dosage (8 sessions) to their target population.

The logic model should fully describe and operationalize the core elements of an intervention or strategy and how these activities work together to prevent HIV. All intervention activities, based on the core elements of the intervention, should address the problem statement and be linked to clearly stated and planned outcomes.

- 4) **Pre-testing** of the intervention materials with an appropriate community advisory board can help to ensure that they are culturally competent and responsive to the needs of the target population. Pre-testing materials should cover a range of considerations including reading level of the target population, community values and norms, and attractiveness of the intervention materials. Health messages and intervention activities should be pre-tested to determine if instructions and messages are understood and retained by the new target audience.
- 5) **Pilot testing** of the revised intervention with a small subgroup of the population gives an indication of the usefulness of the adapted or tailored intervention. Pilot testing can be divided up into small pilots of each core element and then a pilot can be conducted of the entire intervention including all core elements. This strategy works best for individual or group level interventions.

For example in the SISTA intervention, one group level session addresses gender and ethnic pride for African American women. If the intervention is adapted for Hispanic women, this session will need to be adapted for Hispanic women and then pre-tested with a group of Hispanic women before the intervention is implemented in a larger venue by the implementing organization.

Community-level interventions are very difficult to pilot as a full intervention. However, core elements of community-level interventions can be piloted. For example, in the PROMISE intervention, role model stories are distributed by a group of peer advocates to members of the target audience. Before distributing multiple role model stories in the community, the agency that is adapting and tailoring PROMISE should consider piloting the process with a small group of peer advocates that distribute just one role model story. This piloting will help the agency decide on how best to implement the adapted and tailored intervention on a larger scale.

Cultural Competence

Individuals and groups vary considerably by ethnicity, gender, age, sexual orientation, and language, and their experiences may result in cultural orientations that are consistent with these variations. It is important that providers consider the meaning of such cultural variations in the implementation and delivery of programs and services. Culturally competent programs and services result from acknowledging and responding appropriately to the health needs of persons within the context of their diverse cultural experiences.

In 2001, the Office of Minority Health (OMH) in the Department of Health and Human Services published a set of national standards for delivering culturally and linguistically appropriate services (CLAS). OMH began by defining cultural competence as

“A set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals that enables effective work in cross-cultural situations. *Culture* refers to integrated patterns of human behavior that include the language, thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups. *Competence* implies having the capacity to function effectively as an individual and an organization within the context of the cultural beliefs, behaviors, and needs presented by consumers and their communities.”

In order to become culturally competent, providers must value diversity, understand their cultural biases, be conscious of the dynamics that occur when cultures interact, internalize cultural knowledge, and develop adaptations to diversity. The OMH report offers the following standards as the basis for developing and measuring culturally and linguistically competent health programs and services. Organizations should:

- 1) Ensure that clients/consumers receive from all staff members effective, understandable, and respectful care that is provided in a manner compatible with their cultural beliefs and practices and preferred language;
- 2) Implement strategies to recruit, retain, and promote at all levels of the organization a diverse staff and leadership that are representative of the demographic characteristics of the service area;
- 3) Ensure that staff at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery;
- 4) Offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each client/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation;
- 5) Provide to clients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services;

- 6) Ensure the competence of language assistance provided to limited English proficient clients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the client/consumer);
- 7) Make available easily understood, client-related materials and post signage in the languages of the commonly encountered groups and/or groups represented within the service area;
- 8) Develop, implement, and promote a written strategic plan that outlines clear goals, policies, operational plans, and management accountability/oversight mechanisms to provide culturally and linguistically appropriate services;
- 9) Conduct initial and ongoing organizational self-assessments of CLAS-related activities and are encouraged to integrate cultural and linguistic competence-related measures into their internal audits, performance improvement programs, patient satisfaction assessments, and outcomes-based evaluations;
- 10) Ensure that data on the individual client's/consumer's race, ethnicity, and spoken and written language are collected in health records, integrated into the organization's management information systems, and periodically updated;
- 11) Maintain a current demographic cultural and epidemiological profile of the community as well as a needs assessment to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area (the HIV prevention community plan and other sources of relevant information);
- 12) Develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and client/consumer involvement in designing and implementing CLAS-related activities;
- 13) Ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by clients/consumers;
- 14) Regularly make available to the public, information about their progress and successful innovations in implementing the CLAS standards and to provide public notice in their communities about the availability of this information.

The interventions and strategies outlined in this document are presented as best practice models that can guide the services of an organization or agency that delivers services under the recommendations of *Advancing HIV Prevention*. As always, CDC relies upon its partners in the community to deliver effective, culturally relevant services to fight HIV, and will work with these partners to adapt and tailor the interventions in this guidance and in the REP and DEBI programs to meet the needs of the people they serve. The goals of this new initiative are to increase the number of PLWH who know their HIV status and to provide them and people at

high risk of HIV infection with the best available tools to stay healthy and reduce transmission of HIV.

Key Articles and Resources

<http://www.cdc.gov/hiv/partners/ahp.htm>

CDC. Advancing HIV Prevention: New Strategies for a Changing Epidemic. MMWR 2003; 52:329-332

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). National Standards for Culturally and Linguistically Appropriate Services in Health Care.

U.S. Department of Health and Human Services, Public Health Services, National Institutes of Health, National Cancer Institute, Office of Cancer Communications, *Making Health Communication Programs Work: A Planner's Guide*; NIH Publication No. 92-1493, April 1992. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

SECTION 1: Targeted Outreach and Health Education and Risk Reduction

Activities included in this section are intended to help agencies target their recruitment for HIV counseling and testing and other prevention services to persons at high risk for HIV. All recruitment, outreach, and health education and risk reduction activities must be followed with a completed referral into a prevention service. For persons of unknown serostatus or negative persons who have not tested in the past 6 months, this should be a referral for counseling, testing, and referral services.

A major concern in projects that involve community outreach is the safety of street outreach workers. Outreach and health education and risk reduction require peer volunteers and outreach specialists to be out on the streets of their community. The guidelines presented below are ways that the agency can support the safety of their peer volunteers when conducting street outreach:

- Let local authorities know about the project, its logo, its activities, and the people who will be involved in the project.
- Provide identification for project staff and volunteers.
- Whenever possible, arrange for staff and volunteers to work in teams or at least in pairs.
- Keep track of where staff and volunteers are during project activities.
- Based on the knowledge of the community, identify safe places in the community for staff and volunteers to conduct outreach.
- Avoid areas or times of the day that “everyone” knows are dangerous.
- Be sure that staff and volunteers know the best ways to exit the community in an emergency and have emergency numbers to call

PROCEDURAL GUIDANCE FOR RECRUITMENT

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF RECRUITMENT

Recruitment refers to the means by which an agency or organization reaches members of its target population to help them take advantage of HIV prevention interventions, programs, and services. It can be targeted to persons of negative or unknown HIV serostatus at high-risk for HIV (those performing behaviors that put them at risk for HIV or other STDs in high prevalence settings or with HIV-positive individuals) or to people living with HIV. Recruitment can take different forms depending on the most appropriate approach for a given target population and on the needs and abilities of the organization engaging in the activity.

Outreach is a common means of meeting potential high-risk clients in their own environment to deliver HIV prevention messages and services and to bring them into additional prevention services. These activities may take place in specific venues where high-risk individuals congregate and/or in places where high risk behaviors take place (e.g., shooting galleries, the street, parks, bars, bathhouses) or can be conducted at virtual sites including the Internet or telephone hotlines. Finally, outreach can take place as the result of contacts established through the use of social networking techniques that demonstrate connections between high-risk persons. Agencies can work with current clients to reach partners or friends who may also be at high risk.

Within- and between-agency referrals are other common ways for organizations to bring clients to services. Often an agency will use its existing programs or interventions to refer clients to other services within the agency (e.g., one of the goals of an individual level intervention may be to increase a client's acceptance of, or readiness for, testing). A benefit of this strategy is that it takes advantage of the trust that is already developed by clients who have previously been engaged with an agency. When a referral is made to another service within that agency, the client may be more likely to accept and access the referral.

The establishment and maintenance of linkages with referral networks (i.e., interrelated agencies that provide services for high-risk persons, for example service agencies, homeless shelters, or care providers) for between-agency referrals can also be an important tool or strategy for recruiting high-risk persons into HIV prevention interventions. Because persons at risk for transmission or acquisition of HIV often have competing needs which make HIV prevention a lower priority, they may not initiate access to HIV prevention services, but may seek out other services from which they can be referred for HIV prevention interventions. Obtaining a commitment from other service agencies to assess the risk for HIV acquisition or transmission among their clients and make appropriate referrals is an important means of reaching clients in need of prevention services.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Recruitment has 5 core elements which include:

- 1) Use of information from multiple sources to describe common characteristics of the target population, which can be used for targeting recruitment activities.
- 2) Develop and deliver appropriate health messages for the setting (either to be delivered by an outreach worker or by a referral source).
- 3) Recruit for specific services (e.g., counseling, testing, and referral services, PCM, other prevention interventions). Recruitment must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH).
- 4) Track completion of referral to monitor the effectiveness of the referral strategy.
- 5) Revise strategies or venues, as appropriate.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Each strategy for recruitment includes a different set of key characteristics:

Recruitment through *Internal Resources*

- Develop criteria that will trigger a referral from providers of other services within the agency.
- Providers of services within the organization should assess all consumers to determine appropriateness for prevention services delivered within the organization and make appropriate referrals to those services.
- Develop targeted and appropriate messages to be delivered by individual members of an agency or by mass messaging strategies (e.g., on posters hung throughout the agency).

Recruitment through *Referral Networks*

- Establish linkages with those service providers that members of the target population are most likely to access and provide training to these providers related to prevention services.
- Develop formal agreements with appropriate service providers for ongoing screening and bidirectional referrals.
- Provide tailored and appropriate materials to referral agents that advertise programs and services.
- Provide tailored and appropriate materials that describe programs and services to potential clients.

Recruitment through *Outreach*

- Go to venues where potential clients congregate at the times when they are present.
- Conduct outreach in teams to improve the safety of outreach workers.
- Screen clients to determine their needs for specific prevention services (e.g., counseling, testing, and referral (CTR); prevention case management (PCM); or other prevention interventions).
- Develop and deliver tailored and appropriate health and prevention promotion messages.
- Provide tailored and appropriate materials that describe programs and services to potential clients.
- When possible, use peers as outreach workers.

Procedures describe the activities that make up the content of the strategy and provide direction to agencies or organizations regarding the use of the strategy. Procedures for recruitment follow.

Regardless of the type of recruitment strategy employed by an agency or organization, a vital component to consider is the profile of the population to be targeted. The organization must understand the members of its target population in order to devise the most appropriate strategy to reach them. Information from many sources can be used to describe the common characteristics of the population. Agencies should consider reviewing:

- epidemiological profiles,
- key informant interviews,
- focus groups,
- ethnographic data,
- surveys/questionnaires,
- program records, and
- other relevant population-based research.

The target group must be specified at least in terms of gender, age, race/ethnicity, risk behaviors, indicators of risk (such as drug use), and location. This information should be reviewed on a regular basis to ensure that all relevant information is current.

The characteristics of the population should be used to devise appropriate health and prevention promotion messages that can be used to increase the likelihood that prevention services will be accepted and that referrals will be completed. The messages should be specific to the type of service for which the agency is recruiting, should be crafted using the language of the target population, and should be tested with community members to ensure understanding and appropriateness. These tailored messages can then be used in outreach or can be given to other referral sources to be used at their discretion.

For agencies choosing to use outreach as a means of increasing participation in their programs or for referring clients to other programs, additional considerations must be addressed. Using the information gained by completing a profile of the target group, outreach workers must plan their strategies to maximize contact with the target population. When safety considerations (for the worker and the client) permit, workers should go to the venues where potential clients congregate at the times when they are present. Workers must consider the approachability of clients at those venues and should choose those venues where potential clients are likely to be most receptive to the recruitment message. Messages are most likely to be accepted when they come from workers who are similar to the target population; therefore, peers should be used as outreach workers wherever possible. Additionally, it is important that information or materials be made available to clients in a manner that is non-intrusive (e.g., referral cards that are pocket-sized, printed information). Finally, outreach strategies should be used to provide services or access to services (e.g., CTR or prevention counseling) wherever possible. If on-site services are not possible, a referral tracking system must be devised and agencies should consider providing incentives to complete referrals. Agencies developing an outreach program should answer the following questions related to their target populations:

- **Who** is the population, and who is the most appropriate person to provide the service to them? Messages or services coming from peers are more likely to be accepted.
- **What** is the message or service that the agency should be delivering? The agency may use outreach to remove barriers to accessing testing and prevention services or to deliver health education/risk reduction messages with the goal of getting the client into such services.
- **Where** is the appropriate place to approach clients? Agencies must meet the clients in venues in which they are most likely to find the target audience, including venues where high risk behavior is taking place, and in places where their safety is assured.
- **When** should the outreach service be provided? Outreach workers must choose times that are appropriate to find their target audience.
- **How** should the message or service be delivered? Messages can be verbal or written, and can be in the form of pamphlets, flyers, or signs. Services can be delivered by referral, or on site if appropriate.

A specialized form of outreach is the use of community level interventions to reach a targeted population. Community level interventions such as Popular Opinion Leader (POL) and Peers Reaching Out and Modeling Intervention Strategies (Community PROMISE) involve using peers to deliver prevention messages to the broader community. These prevention messages may be in the form of personal endorsements of behavior change (POL) or in the form of role model stories that are distributed in a community (Community PROMISE) but the messages can be used to

encourage testing, involvement in prevention services at an organization, or adoption of safer behaviors. Agencies interested in these strategies are referred to the Disseminating Effective Behavioral Interventions (DEBI) project website at <http://www.effectiveinterventions.org>.

Agencies may also choose to rely on referral networks for recruiting clients instead of, or in addition to, outreach. For these agencies, linkages to other agencies and providers should be formalized and nurtured. Agencies should solicit memoranda of agreement, should ensure that referral sources are familiar with their services (perhaps through in-service presentations or informational pamphlets that can be distributed to referral sources), and should keep all contact information up-to-date for the organization. If the referral sources are unable to provide the referrals that would be expected, the agency should attempt to diagnose the barrier to effective referral and develop a strategy to address it.

Agencies that are unable to provide extensive services beyond recruitment should partner with other organizations that provide HIV prevention services. Agencies that provide services but do not have, or have limited capacity to conduct recruitment should consider partnering with organizations that can offer this expertise.

RESOURCE REQUIREMENTS

Staffing for recruitment programs should be determined based on a needs assessment and the epidemiological profile of the target population (the HIV prevention community plan and other sources of relevant information). In general, agencies should devote 1.0 full-time equivalent (FTE) position to maintaining a referral network, including ensuring that referral sources are active, tracking referrals made by recruitment program staff, and assessing client satisfaction with referrals provided. Depending on the size of the network in a given area, this FTE may also be responsible for supervision of recruitment program staff. Recruitment by outreach should be conducted by teams rather than individuals; therefore if an agency chooses to include outreach, at least 2.0 FTEs will be required to deliver this service. Recruitment needs will determine the staffing level for an area. The agency must assure that supervision is adequate for the number of outreach workers employed. In general, the ratio of supervisors to outreach staff should be 1:10.

PHYSICAL SETTING CHARACTERISTICS

Regardless of the recruitment strategy chosen the physical setting of the recruitment services is always dependent on the population targeted. As a rule, recruitment strategies meet the client wherever he/she is to bring him/her into services, which may or may not be located in the same area. Within these guidelines, providers should identify locations where clients feel their privacy and confidentiality will be maintained and respected.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to engage in recruitment, the following policies and procedures should be in place to protect clients, the agency, and the individual workers:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data, behavioral and clinical surveillance, and the state or local HIV prevention plan. Persons living with HIV are the first priority population for community planning groups, and services for persons living with HIV should be addressed as such.

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Linkage of Services: Recruitment must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: For agencies conducting outreach, a code of conduct must be established. This code should include, but not be limited to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both agencies and clients should be in place when implementing recruitment:

Agencies: Agencies should have in place a mechanism to ensure that all appropriate protocols for recruitment are followed. These protocols include 1) the method for collecting information to select the target population, 2) records of formal or informal agreements with other agencies, 3) training for referral/outreach staff, 4) procedures for tracking referrals including the number completed and barriers for those not completed, and 5) staff supervision. Quality assurance activities can include direct observation and review of client interactions by key staff involved with the activity. This review should focus on adherence to referral protocols, accessibility and responsiveness to expressed client needs, documentation of contact, and follow-up on referrals.

Client: When appropriate, clients' satisfaction should be assessed upon completion of referrals.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.A-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.
 - **I.B-** The proportion of person who access counseling and testing from each of the following interventions: individual level interventions and group level interventions.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
 - **V.A -** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

NIDA Outreach Manual. To obtain copies, contact: The National Clearinghouse for Alcohol and Drug Information. PO Box 2345, Rockville, MD 20847 (1-800-729-6686) or visit <http://www.drugabuse.gov>.

Disseminating Effective Behavioral Interventions <http://www.effectiveinterventions.org>.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (1994). Planning and conducting street outreach process evaluation.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (1998). What we have learned from the AIDS evaluation of street outreach projects. (1-888-232-3228, press 2, 5, 1, and 1 as prompted and request “What we have learned” from AESOP).

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). National Standards for Culturally and Linguistically Appropriate Services in Health Care.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF POPULAR OPINION LEADER (POL)

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF POPULAR OPINION LEADER

Popular Opinion Leader (POL), consists of a group of trusted, well-liked people who are recruited and trained to conduct a specialized type of outreach. This outreach includes endorsement of safer sexual behaviors in casual, one-on-one conversations with peers in their own social network at a range of venues and settings.¹ This intervention has been packaged by CDC's Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

POL was initially demonstrated to increase condom use in men who have sex with men and the intervention techniques can be adapted to a range of risk populations in a broad range of venues. In addition, this specialized form of outreach can be used to diffuse messages on a range of health behaviors through a community. For example, messages about HIV antibody testing, status disclosure, linkage to prevention and medical services may be diffused through this intervention.

During peer-to-peer conversations, the trained popular opinion leader corrects misperceptions, discusses the importance of HIV prevention, describes strategies he/she uses to reduce risk (e.g., keeping condoms nearby, avoiding sex when intoxicated, resisting coercion for unsafe sex), and recommends that the peer adopt safer sex behaviors, seek antibody testing, consider status disclosure to sexual partners, and/or seeks medical care if they are HIV positive. Popular opinion leaders may wear buttons, caps, jacket logos, t-shirts, key chains, or temporary tattoos displaying the project logo. The logo may also be used on posters around the community venues, as a conversation-starting technique. Each leader agrees to have at least 14 conversations and to recruit another popular opinion leader. It is important to recruit and train 15-20% of the persons in each social network in the target population into the POL program so that risk reduction and other health behaviors become normative and are diffused throughout the target population. Agency facilitators do the preparatory work and teach vital communications skills but it is through the efforts of community members that the community changes the way it thinks about protecting itself from HIV.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently

must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. The 3 core elements of POL include:

- 1) Identification and enlistment of popular and well-liked opinion leaders to take on risk-reduction advocacy roles.
- 2) Training for cadres of opinion leaders to disseminate risk-reduction endorsement messages and prevention service utilization within their own social networks.
- 3) Support and reinforcement of successive waves of opinion leaders to help reshape social norms to encourage safer sex, antibody testing, disclosure HIV status to sexual partners, and finding and accessing medical care if HIV positive.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. POL has the following key characteristics:

- Elicit the involvement, support, and cooperation of key “gatekeepers” in the community
- Identify and characterize the various social networks within the target population
- Using key informants, identify enough popular opinion leaders to equal at least 15% of each identified social network in the population. This percentage has been documented as the point at which social norms begin to shift.
- Provide training to opinion leaders on the following skills and knowledge:
 - Theory and philosophy of the intervention
 - Accurate information on HIV risk reduction
 - Practical advice on how to implement HIV risk reduction behavior changes
 - Communication skills for imparting HIV risk reduction information to others, including modeling and role-playing
 - Initiation of effective peer risk reduction conversations
- Seek the agreement of each opinion leader to have a specified number of conversations (e.g., 14) with at-risk friends and acquaintances within a specified period
- Place posters in the intervention venue and give opinion leaders buttons to wear when in the venue
- Recruit additional opinion leaders by asking each current opinion leader to bring friends to participate in the next wave of the intervention
- Train a new wave of opinion leaders to maintain program momentum
- Organize “reunion” meetings with all opinion leaders (first and successive waves) and key community gatekeepers to discuss maintenance of POL

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the conduct of the intervention. Procedures for POL follow:

Opinion leaders are identified and recruited from all of the major social networks in the target population. After recruitment, they attend four training sessions during which they discuss HIV/AIDS facts and myths, receive practical advice for changing behaviors, and learn and practice ways of reinforcing safer sex norms through risk reduction conversations with their friends and acquaintances. At these training sessions opinion leaders are taught how to endorse antibody testing and the desirability of knowing one's antibody status and describe their experiences in obtaining an HIV antibody test. They are also trained to encourage participation in partner counseling and referral services and status disclosure with future sexual partners and to endorse taking steps to access medical care if one is HIV positive.

For a CBO to maintain the intervention over time, each opinion leader in the first group is asked to invite two or more friends to attend the next training cycle. This second wave of opinion leaders begins the training as the first group finishes. When the second group completes the training, it recruits the third wave of opinion leaders. In this way, each group of opinion leaders invites the next and the intervention continues to diffuse health norms. As the number of trained opinion leaders increases, the number of conversations in the community that endorse safer sex, antibody testing, status disclosure, and seeking medical care if HIV positive also increases.

Before implementing POL, CBOs should elicit the involvement, support and cooperation of key community gatekeepers (i.e., leaders in the community) who help identify the popular opinion leaders and offer support for the intervention and its goals. The CBO staff implementing POL should then identify and characterize the various social networks within the population at risk. CBO staff then recruits opinion leaders by emphasizing their potential positive role as a popular resource to others in their community.

During POL training sessions, provide opinion leaders with:

- accurate information about HIV risk reduction,
- antibody testing technologies including rapid testing,
- the importance of partner counseling and referral services as a prevention strategy,
- the importance of status disclosure to sex partners, and
- the importance of seeking medical care if a person finds they are HIV positive.

Also during POL training sessions, provide opinion leaders with practical advice on how to implement HIV risk reduction behavior changes or how to seek antibody testing. An important aspect of POL training sessions is building the communication skills of the opinion leaders so that they can effectively communicate HIV risk reduction information to others in spontaneously initiated conversations. This is done by modeling the conversations during training and then providing opportunities for participants to role play and receive feedback on their conversations. Practicing safer sex, obtaining an HIV antibody test, disclosing HIV status, and seeking medical care if HIV positive are not topics that typically arise in casual conversations, so POL training must facilitate group problem-solving centered around how each opinion leader will initiate peer

conversations, allowing each person ample time to discuss issues particularly relevant to him or her. At the end of the POL training sessions, seek the agreement of each opinion leader to have a specified number of conversations with at-risk friends and acquaintances. CBO staff can recruit additional opinion leaders by asking each current opinion leader to bring friends to participate in the next wave of intervention trainings.

RESOURCE REQUIREMENTS

Because POL is an intervention that relies heavily on volunteers, an agency's staffing requirements are limited. Staff activities revolve around:

- identifying venues where the target population congregates,
- identifying the social networks within the population and each network's opinion leaders,
- recruiting and training successive waves of opinion leaders,
- providing materials that display the conversation-starting logo,
- hosting reunion parties for opinion leaders and gatekeepers, and
- maintaining quality assurance.

The annual staffing requirements include 200 hours of senior staff time, 202 hours of junior staff time, and 19 hours of administrative assistant time. These figures do not include time spent by gatekeepers who assist in identifying opinion leaders or the time spent by the opinion leaders to attend trainings, conduct risk reduction conversations, and recruit additional opinion leaders.

RECRUITMENT

The original target population for POL was gay men in mid-size cities but the intervention can be adapted to reach a broad range of populations and groups at risk.

Agencies wishing to implement POL should review the Procedural Guidance for Recruitment in this document to choose a recruitment strategy that will work in the setting in which they plan to implement POL.

PHYSICAL SETTING CHARACTERISTICS

The intervention needs a place to hold POL trainings and staff meetings. Ideally the place should have comfortable seating for having discussions and viewing videos. Staff meetings can be held in the CBO's office space. POL trainings should be held at the same place for each session, but the choice of location can vary. Some programs have held training sessions at an intervention venue during the hour before the venue opened for business. Agencies implementing POL should choose a training location that is easily accessible from public transportation routes. The opinion leaders' risk reduction conversations take place in community venues where the target population lives, works, and socializes.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement POL the following policies and procedures should be in place to protect clients, the agency, and the opinion leaders:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data, behavioral and clinical surveillance, and the state or local HIV prevention plan created with input from the state or local community planning group(s).

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Linkage of Services: Recruitment and health education and risk reduction must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care*, which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: Agencies conducting recruitment, outreach, and health education and risk reduction, must established a code of conduct. This code should include, but not be limited to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

The following quality assurance activities should be in place when implementing POL:

- 1) **Implementation plan** to ensure that POL's core elements and key characteristics are all included and followed.
- 2) **Hands-on guidance** to improve opinion leaders' skill and comfort in initiating and conducting risk reduction endorsement conversations with friends and acquaintances within their own social networks.
- 3) **Training of staff and skills development** to ensure that staff thoroughly understand the intervention and its underlying theory, know correct risk-reduction information, identify social networks and their opinion leaders, have group facilitation skills, recruit and train successive waves of opinion leaders, and maintain and evaluate the intervention.
- 4) **Fidelity to Core Elements** to ensure program effectiveness. Agencies must not alter, ignore, add to, or change POL's core elements.
- 5) **Quality Assurance Fidelity Checklist** to track whether all of POL's key characteristics were followed.
- 6) **Customer Satisfaction Survey** conducted at regular intervals of the agency's choosing to measure the target population's exposure to and acceptance of the intervention and any changes they have made to their behaviors.
- 7) **Feedback Loops** to improve delivery of the intervention to the target population. Information on the impact of the intervention should be shared with opinion leaders whenever possible to encourage their continued involvement.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include:

- Collecting and reporting standardized process and outcome monitoring data consistent with CDC requirements
- Entering and transmitting data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements

- Collecting and reporting data consistent with the CDC requirements to ensure data quality and security and client confidentiality
- Collaborating with CDC in assessing the impact of HIV prevention activities by participating in special projects, upon request.

KEY ARTICLES AND RESOURCES

¹Kelly JA, St. Lawrence JS, Diaz YE, Stevenson, LY, Hauth AC, Brasfield TL, Kalichman SC, Smith JE, Andre ME. (1991). HIV risk behavior reduction following intervention with key opinion leaders of population: An experimental analysis. *American Journal of Public Health*, 81(2), 168-171.

Kelly JA, St. Lawrence JS, Stevenson Y, Hauth AC, Kalichman SC, Diaz YE, Brasfield TL, Koob JJ, Morgan MG. (1992). Community AIDS/HIV risk reduction: The effects of endorsement by popular people in three cities. *American Journal of Public Health*, 82 (11), 1483-1489.

Kelly JA, Murphy DA, Sikkema KJ, McAuliffe TL, Roffman RA, Solomon LJ, Winett RA, Kalichman SC, and the Community HIV Prevention Research Collaborative. (1997). Randomized controlled community-level HIV-prevention intervention for sexual risk behavior among homosexual men in US cities. *The Lancet*, 350, 1500-1505.

Miller RL, Klotz D, Eckholdt HM. HIV prevention with male prostitutes and patrons of hustler bars: Replication of an HIV prevention intervention. *American Journal of Community Psychology*, 26(1), 97-131.

Implementation materials and training and technical assistance for POL are available through the Dissemination Effective Behavioral Interventions program and can be accessed on the Internet at www.effectiveinterventions.org.

For more information on intervention, training and technical assistance, or to get your name on a list for a future training, please go to the website: www.effectiveinterventions.org

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF THE MPOWERMENT PROJECT

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF THE MPOWERMENT PROJECT

The Mpowerment Project¹ is a community-level HIV prevention program that is run by a “Core Group” of 12 - 20 young gay/bisexual men from the community and paid intervention staff (coordinators). The young gay/bisexual men from the Core Group, along with other volunteers, design and carry out all project activities. Ideally, the project has its own physical space where most outreach events and meetings are held and which serves as a drop-in center where young men can meet and socialize during specified hours. The program relies on a set of four integrated activities:

- *Formal Outreach:* Teams of young gay/bisexual men go to locations frequented by young gay men to discuss and promote safer sex, deliver educational/informational literature on HIV risk reduction, and distribute condoms. Additionally, the team creates its own informational events to educate young gay men (e.g., discussion groups) at which safer sex can be promoted.
- *M-groups:* These peer-led, one-time, 3 hour meetings of 8-10 young gay/bisexual men discuss factors contributing to unsafe sex among the men (e.g., misconceptions about safer sex, poor sexual communication skills). Through skills-building exercises, the men practice safer sex negotiation role-play and correct condom use. Participants receive free condoms and lubricant and are trained and motivated to conduct informal outreach.
- *Informal Outreach:* Informal outreach consists of young men discussing safer sex as well as the importance of knowing one’s serostatus and being tested for HIV with their friends in a relaxed, informal manner that promotes community norms. Informal outreach can also target other community norms such as the desirability to know one’s HIV antibody status and take an HIV antibody test, or to disclose HIV status to potential sex partners, or to seek medical care if one is HIV positive.
- *Ongoing Publicity Campaign:* The campaign attracts men to the project by word of mouth and through articles and advertisements in gay, alternative or university newspapers.

The Mpowerment Project has been shown to reduce rates of unprotected anal intercourse among young gay/bisexual men in communities in which it has been implemented.^{1,2}

The Mpowerment Project training manuals and video tapes are available by contacting mpowerment@psg.ucsf.edu or on the Internet at mpowerment.org. The program developers at the University of California San Francisco's Center for AIDS Prevention Studies offer low-cost, experiential trainings 3-4 times each year for project coordinators and program supervisors. Additionally, eligible organizations may also obtain free, on-going technical assistance from the CAPS team. TA providers are former Mpowerment Project coordinators who have extensive hands-on experience with the program and are trained to deliver personalized assistance.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. There are eight core elements and one optional element for the Mpowerment Project:

- 1) Maintain a Core Group of 12-20 young gay men to design and carry out project activities.
- 2) Recruit volunteers to assist in the delivery of services and to make important decisions about the program
- 3) Use project coordinators to oversee project activities
- 4) Establish a project space where many of the project activities can be held
- 5) Conduct formal outreach including educational activities and social events
- 6) Conduct informal outreach to influence behavior change
- 7) Convene peer-led, one-time discussion groups (M-groups)
- 8) Conduct a publicity campaign about the project within the community

Optional Element

- 1) Convene a community advisory board

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. Key Characteristics of the Mpowerment Project are:

Core group:

- Makes important decisions
- Bases decisions on the project's guiding principles
- Membership has racial/ethnic/socioeconomic diversity
- Membership may change over time as new men join and men who have been in Core Group leave
- Supports and encourages each other and other friends about safer sex
- Meetings are fun, social, productive, and scheduled regularly
- Engages in reflective analysis of all parts of the project, its own role in the project, and issues facing young gay/bisexual men.

Volunteers:

- Represent diverse racial/ethnic/socioeconomic backgrounds
- Make important decisions
- Learn new skills and conduct meaningful/interesting work
- Support and encourage each other and other friends about safer sex
- Encounter a warm, appreciative, social, and welcoming atmosphere

Coordinators:

- Understand HIV prevention and community building
- Are knowledgeable about the local young gay/bisexual men's community
- Demonstrate leadership skills
- Oversee all Project activities
- Promote diverse racial/ethnic/socioeconomic involvement
- Support the Core Group and volunteers to develop and implement activities
- Begin the safer sex diffusion process
- Engage in reflective analysis of all parts of the project, their own role in the project, and issues facing young gay/bisexual men

Project space:

- Is safe and comfortable
- Is in an accessible, and appealing location.
- Displays safer sex posters and literature are displayed.
- Makes condoms and lubricants available.
- Makes referral information available
- Rapid testing may be offered in this space if privacy and confidentiality is ensured.

Formal Outreach:

- Promotes safer sex, HIV antibody testing, HIV status disclosure
- Sponsors appealing events and engaging performances
- Helps build community
- Provides social opportunities
- Creates opportunities for positive peer influence
- Recruits for M-groups and other project activities
- Empowers project volunteers
- Are scheduled regularly

Informal Outreach:

- Diffuses a norm of safer sex and testing for HIV
- Uses peer influence to change behavior
- Is achieved through non-judgmental and supportive peer interactions
- Is reinforced through other project activities

M-groups

- Facilitated by well-trained and skilled project staff and/or volunteers

- Address young gay/bisexual men's important issues
- Create social opportunities
- Teach safer sex education
- Teach and motivate informal outreach
- Teach sexual negotiation skills
- Encourage project involvement and volunteerism
- Are scheduled regularly

Publicity campaign

- Creates attractive informative materials
- Reminds young gay/bisexual men of the importance of safer sex, encourages HIV testing, and seeking medical care if HIV positive.
- Reaches all young gay/bisexual men in the community
- Targets young gay/bisexual men, not the general community.

Community Advisory Board (optional element)

- Includes 5 – 10 individuals, who are typically older than 30, who are knowledgeable about target population, public health in state and community, prior HIV prevention efforts, or other community institutions that reach target population
- Serves as a resource to Core Group
- Does not have day-to-day decision-making power

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for the Mpowerment Project follow.

Agencies begin the process of delivering the Mpowerment Project by first locating coordinators for the project by writing letters to agencies, and placing ads in local gay/bisexual, alternative, and university newspapers. Project coordinators are then hired and trained to be responsible for organizing all aspects of the intervention, including managing volunteers and all activities. They also influence the diffusion process of safer sex messages including messages about the importance of HIV testing. They facilitate the empowerment of the young men who join the project as Core Group members or volunteers.

Next, the agency conducts a community assessment which helps to identify:

- The different groups of young gay/bisexual men throughout the community (including what social spaces exist and where the different groups hang out)
- Resources (e.g., spaces in which to hold outreach events, especially those that attract young gay/bisexual men)
- People in the community who are relevant to the project (e.g., potential Community Advisory Board members, organizations that might support the project, places where you can advertise to or recruit young gay/bisexual men)

After the community assessment, agency representatives must contact community leaders and inform them of the project.

The Mpowerment Project is run by a volunteer Core Group of 12 to 20 young gay/bisexual men from the community. To assemble the Core Group, project leaders must first identify potential Core Group members from the different segments of the young gay/bisexual men's community, and second, describe the program to them and invite them to join the Core Group. The Core group meets weekly and with the assistance of additional volunteers can make key project decisions. These include naming the local project, planning intervention activities and developing materials. In cooperation with the coordinator, they also choose the project space and furnish it.

Volunteers from the young gay/bisexual men's community carry out most activities. They usually do not devote as much time as the Core Group members but their input into and help with activities is essential. Volunteers support each other and stress the importance of consistent safer sex and of HIV testing. Depending on funding levels, a stand-alone project housed by a CBO is the most typical structure. However a consortium of community agencies could sponsor the intervention.

The Core Group is also assisted by a Community Advisory Board which meets monthly to offer advice on intervention activities to the Core Group and the Project Coordinators. They also link the project to a range of community agencies.

Formal outreach includes outreach teams and outreach events. Outreach teams of young men go to venues to promote safer sex. They may drop in on a specific venue for very brief activities that attract attention and promote safer sex. A major aspect of formal outreach is the creation of events that will attract young gay/bisexual men and where safer sex can be promoted. The intervention sponsors a range of large and small outreach events designed to appeal to each segment of the young gay/bisexual men's community. These activities can include weekly video presentations, social gatherings, discussion groups, and community forums. The outreach events are designed to attract young gay/bisexual men to the project so that they can receive appropriate safer sex promotion and referral to HIV counseling, testing, and referral services. Safer sex and HIV testing messages are always infused into every project activity in an appealing and fun way. The outreach team uses entertaining approaches to educate young men about safer sex and encourage them to learn their HIV status, and adopt and maintain safer behaviors over time. The intervention also develops materials for distribution at events. These include safer sex information with motivational messages, condoms, water-based lubricants and invitations to intervention activities. Young men who attend the events can be invited to join the Core Group and participate in M-groups which may be led by a coordinator or by other peers if additional group leaders are needed. Young men desiring to join the Core Group or volunteer are encouraged to attend an M-group as an entry to the project, in order to learn about the project's goals and activities. The project should strive to recruit 15-20% of the estimated number of young gay/bisexual men in the community to attend an M-group so that safer sex norms can be conveyed through the community's social networks and bring about community-wide change.

Informal outreach consists of young gay/bisexual men communicating with friends in casual conversations about the need to engage in safer sex, know their HIV antibody status, disclose to potential sexual partners, and seek medical care if HIV positive. The goal is to develop a process of communication that promotes safer sex across the entire community. Young men learn how to

conduct informal outreach while attending the M-groups. They are asked to make a commitment to speak with several of their friends, give them safer sex packages, and invite them to an M-group.

An ongoing publicity campaign communicates project goals, health messages, and activities. Publicity campaigns use articles and advertisements in the alternative press, including gay and university newspapers; posters and fliers; internet web pages, chat rooms, e-mail distribution lists; and word of mouth publicity within social networks. The publicity campaign's goals are to establish awareness of the intervention; invite young men to become involved; and provide a continual reminder of safer sex norms.

RESOURCE REQUIREMENTS

Coordinators are responsible for organizing all aspects of the intervention, including recruiting Core Group members and volunteers and managing all personnel and activities. The original researchers recommend hiring at least 1.5 FTE coordinators should to manage the program. The needs of the program and community characteristics will dictate the number of coordinators that are needed. An administrative employee (e.g., HIV prevention manager) of the CBO typically supervises the Project Coordinator(s).

The intervention is designed by a Core Group of volunteers which should include young gay/bisexual men who are representative of the diversity of the population of young gay/bisexual men in the community. The volunteers also facilitate M-groups and plan all events related to the intervention.

Besides staff salaries, the major expense related to the delivery of the Mpowerment Project is the need for a dedicated space for the intervention which must be furnished and decorated, and should contain a VCR and television for use in groups. This space serves as a headquarters for the project, and as a community center for young gay and bisexual men. The project space is where the project holds most of its outreach events and staff meetings. During certain hours it also serves as a drop-in center where young men can socialize, get information about community organizations and services, obtain referrals, and obtain safer sex materials. HIV testing may be offered if privacy and confidentiality can be assured.

RECRUITMENT

The target population for the Mpowerment Project is young gay and bisexual men (ages 18-29). Recruitment for the M-groups, the core group, the community advisory board is accomplished through both formal and informal outreach, and through use of an ongoing publicity campaign. Agencies choosing to implement the Mpowerment Project, should also review the Procedural Guidance for Recruitment in this document to choose a recruitment strategy that will work in the setting in which they plan to implement the Mpowerment Project.

PHYSICAL SETTING CHARACTERISTICS

The target population for the Mpowerment Project is young gay and bisexual men (ages 18-29). Recruitment for the M-groups, volunteers the Core Group and to the informational activities is accomplished through both formal and informal outreach, and through use of an ongoing publicity campaign. Agencies choosing to implement the Mpowerment Project should also review the Procedural Guidance for Recruitment in order to choose a recruitment strategy that will work in the setting in which they plan to implement the Mpowerment Project. Additional training and technical assistance about recruitment for the Mpowerment Project are available from the original research team at the Center for AIDS Prevention Studies.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement the Mpowerment Project the following policies and procedures should be in place to protect participants, the agency, and the Mpowerment Project intervention team:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in accessible language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and, if appropriate, a legal guardian if the participant is a minor or unable to give legal consent. Client participation either as a volunteer, a Core Group member, or an M-group member must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that the Mpowerment Project is an intervention that may deal with disclosure of HIV status. Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to assure that the confidentiality of those who choose to participate in the program is maintained.

Data security: All process and outcome data collected from or associated with participants (including worksheets, progress reports, attendance records, etc.) must be kept in a locked, secure location with only designated program staff able to access it.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and

implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants as necessary. Providers must know about referral sources for prevention interventions/counseling (Prevention Case Management, Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

Volunteers: The Mpowerment Project uses volunteers to conduct the intervention; therefore the agency should know and disclose how their liability insurance and worker's compensation applies to those volunteers.

QUALITY ASSURANCE

Quality assurance activities for both coordinators and participants should be in place when implementing the Mpowerment Project:

Coordinator: Training for coordinators should address the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practice of mock Core Groups and M-groups. It is preferred, though not required, that Supervisors of Coordinators also attend a training workshop, which includes a review of the intervention theory and materials. Agencies should have in place a mechanism to assure that all session protocols are followed as written. QA activities can include direct or videotaped observation and review of sessions by key staff involved with the activity. This review should focus on adherence to session content, use of appropriate videotapes with adequate facilitation of discussions; accessibility and responsiveness to expressed participant needs; and important process elements (e.g., time allocation, clarity). Selected intervention record reviews should focus on assuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants when required, and session notes are of sufficient detail to assure that clients are participating actively.

Participants: Participants' satisfaction with the intervention and their comfort should be assessed after each M-group. Process monitoring systems should also track the number of sessions each participant attends, as well as reasons for non-attendance. Process monitoring should also track the frequency of M-groups, Core Groups and outreach events, the numbers and diversity of individuals attending each activity, and track the process of developing outreach events.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.

Project may also want to evaluate and monitor intervention activities using process evaluation methods developed specifically for the intervention:

- These include process evaluation methods designed specifically for M-groups, Formal outreach, Core Group, and publicity;
- These process evaluation forms are designed to be used by the Coordinators and Core Group for reflecting upon success of the project and for redesigning groups and publicity over time

KEY ARTICLES AND RESOURCES

¹Kegeles SM, Hays RB, Coates T.J. (1996). The Mpowerment Project: A community-level HIV prevention intervention for young gay men. *American Journal of Public Health*, 86(8), 1129-1136.

²Kegeles SM, Hays RB, Pollack LM, Coates T.J. (1999). Mobilizing young gay/bisexual men for HIV prevention: A two-community study, *AIDS*, 13(13), 1753-1762.

Resources

Hays, RB, Kegeles, SM, Rebchook, GM. The Mpowerment Project: community-building with young gay and bisexual men to prevent HIV. *American Journal of Community Psychology*, 2003; 31, 301-312.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF THE REAL AIDS PREVENTION PROJECT (RAPP)

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF RAPP

The Real AIDS Prevention Project (RAPP) is a community-level HIV prevention intervention designed to help low-income women (aged 15-34) and their partners reduce their risk for HIV infection. The intervention objectives are to increase consistent condom use by women and their partners, to change community norms so that practicing safer sex is seen as the acceptable norm, and to involve as many people in the community as possible. The program has two phases: 1) community assessment, which involves finding out about the community and how to talk to women and their partners about their risk for HIV infection, and 2) recruitment, which involves the community in a combination of risk reduction activities directed toward these women and their partners. This intervention has been packaged by CDC's Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

RAPP has been demonstrated to be effective in helping women change their behavior. The intervention is based on the Transtheoretical Model of Behavior Change, popularly known as "Stages of Change."^{1,2} This theory says that people do not change behavior all at once, but go through a series of stages. Women in the study were helped to move toward consistent condom use by being given condoms and messages tailored to their stage of change. Two other theories guided the RAPP activities. The Motivational Theory says that people are more likely to adopt new behaviors when influential members of the community have already adopted them,³ and the Social Cognitive Theory says that people learn new behaviors best when trusted sources, such as their peers practice the behavior and when people have the opportunity to increase both knowledge and skills related to the behavior.⁴

Research has indicated that, after participating in the RAPP intervention, women living in high-risk intervention communities were more likely than the women in the comparison communities to have initiated condom use with their steady partners and negotiated condom use with steady and casual partners. Women at very high risk (sex workers) were more likely to use condoms consistently with both steady and casual partners.⁵⁻⁹

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. There are 5 core elements of RAPP:

- 1) Recruit people from the community to become part of the peer network and volunteer several hours each week to talk to women and men about HIV prevention and related issues.
- 2) Conduct encounters that are one-on-one conversations led by trained peer volunteers who ask questions about attitudes and condom use to find out the person's stage of change. Then, based on the response, the peer volunteers give women a message aimed at encouraging them to begin or continue condom use.
- 3) Disseminate role model stories that are based on interviews with people about their decision to change their behavior.
- 4) Recruit local businesses, organizations and agencies to become part of the community network to support the project's goals such as displaying and/or distributing role model stories and other educational materials and sponsoring activities.
- 5) Conduct small-group activities to promote safer sex and host HIV/AIDS presentations. Recruitment for participation in the small group activities is central to the outreach activities of RAPP.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. RAPP has the following key characteristics:

- Hire an outreach specialist who is a recognized leader in the project community. The outreach specialist coordinates the project activities, conducts outreach, and manages the peer network and community network.
- Conduct a community assessment to identify the best ways and places to reach community members and to build interest in the project.
- Recruit community members and interview them about the experiences that made them think about, decide to start, start, or continue to change their behavior.
- Write short role model stories, based on the interviews, about people in different situations and stages of change regarding condom use.

- Train peer volunteers to have one-on-one conversations with members of the target population during which the volunteer asks questions about attitudes and condom use to find out the person's stage of readiness to change.
- Have peer volunteers distribute condoms, role model stories, and other educational materials during the stage-based discussion.
- Conduct presentations for larger groups, such as members of organizations, employees at businesses, and staff or clients of local agencies, to educate community members about HIV and ways to prevent infection.
- Debrief peer volunteers regularly to identify and address problems, support each other, and assess progress.
- Provide short booster trainings for peer volunteers to review information and develop new skills. Trainings can be on topics other than HIV and condoms.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention.

The first phase of the project is **Pre-Implementation** or **Getting Started**. This phase involves the preparations that are made to begin the project activities and usually takes two to four months. These activities include conducting a community needs assessment, arranging for materials to hand out, and recruit and train peer volunteers. The first step of the community assessment is to identify key community members and soliciting community involvement. A promotional video can be used when describing the project with community groups since it was designed to give an overview of the project and to get people excited about RAPP.

The second step of the community assessment is knowing your community. Knowing the community involves not only identifying physical boundaries and collecting information about who lives in it, but also finding out what members think about HIV prevention, what they see as the issues related to HIV, what the barriers are to changing their beliefs and attitudes, and what their ideas are about overcoming these barriers.

Agencies implementing RAPP should conduct **Focus Groups** and **Key Participant Interviews** to gather information about what people want to know about HIV prevention, what messages they want to hear and how they want to hear them. Focus groups are discussion groups that include people who are invited because of their knowledge about a specific topic.¹⁰⁻¹¹ Include people who know a lot about the community and can provide information about community attitudes and perceptions. Their insights can help agencies plan ways to adapt RAPP so it meets the needs of the community in a way that is acceptable to the people who live there. In addition, focus groups can point out some obstacles agencies may face in implementing RAPP as well as strategies to overcome them.

Agencies should conduct at least four focus groups, with eight to ten people from the community. To get the widest range of opinions, the focus groups should be conducted with the following people: community leaders and other influential people who can “make or break” the project, adult females who can share issues specific to women, adult males who can provide insights from the male perspective, and teenagers. A key component to having successful focus

groups is having a trained group facilitator lead and direct the group discussions. Agencies should provide or seek training for inexperienced staff that will conduct the focus groups.

Key participant interviews are one-on-one interviews conducted with people who know about the community and about the people who will be affected by the project's activities. In the interviews, participants should be asked about attitudes, beliefs and perceptions related to HIV prevention. Recognized community leaders, residents of the community, and people with alternative lifestyles such as sex workers should be interviewed. Key participant interviews can be done during the same time period as the focus groups. Agencies should plan to complete both in six to eight weeks.

The second phase of RAPP is **Implementation or Running the Project**. This phase includes implementing outreach activities that make up the project, tracking them, getting feedback from volunteers, and making adjustments. Agencies should begin distribution of role model stories by peer network volunteers as well as recruitment of the community network in the third or fourth month of the project. In the fourth or fifth month, agencies should begin to conduct stage-based encounters, develop new role model stories, and recruit hosts for safer sex programs and sponsors for HIV presentations.

Outreach is a major part of RAPP. It can take on several forms, as described below.

The Peer Network: The Peer Network is one of the 5 core elements of RAPP. It is a group of six to eight community members who volunteer two or three times a week to go out in the community, talk to people about safer sex and hand out role model stories, educational materials, and condoms. A paid outreach specialist manages their activities. To create a peer network, agencies will need to recruit members of the community, orient them to the project and give them training for street outreach, stage-based encounters and other activities they will do in the community.

Active recruiting and training for the peer network should be conducted at least twice a year because dropouts may occur. Agencies should employ the following strategies for maintaining their peer network: identify responsibilities early, provide incentives such as gift certificates, provide a special bag for volunteers to carry their materials in, certificates for completed trainings, and ongoing support.

Stage-Based Encounters: A stage-based encounter is a specific kind of outreach activity that is based on the Stages of Change Theory. It is one-on-one, face-to-face, mini-interview aimed at helping women think about changing a risky behavior, such as having unprotected sex, or maintaining a healthy behavior, like using condoms all the time.

In a stage-based encounter a trained interviewer (a peer volunteer or outreach specialist) asks a few questions to determine readiness for behavior change. Then the interviewer responds in a way that will help the person change a behavior or continue doing the new behavior. This process is called staging. Stage-based outreach involves five things: (1) Making contacts where people in the community live, work, and play; (2) asking a few simple questions to find out if people are using condoms; (3) determining the person's stage; (4) responding in a way that gives

information, encouragement and/or positive feedback specific to the person's stage of behavior change; and (5) handing out role model stories and condoms.

Peer volunteers and the outreach specialist should carry role model stories and condoms every time they go out to do street outreach. Sometime during the stage-based encounter they should offer the person to whom they are talking a story, a condom, and information on where to get counseling and testing for HIV or help with other problems. This type of encounter should take about five to ten minutes.

Agencies implementing RAPP should conduct a two-day training to introduce stage-based encounters for everyone in the peer network. This training should cover the stages of change, influencing factors, strategies for staging, and instructions for reporting the activity.

Role Model Stories: The dissemination of role model stories within a community is a very important part of RAPP outreach. Role model stories are printed stories based on interviews with people about their decision to change their behavior. RAPP role models are people who have decided to practice safer sex and who share their story about why they changed their behavior. In these stories, people in different situations and stages of change tell about real-life experiences that made them think about, start, or continue using condoms. Because role model stories are based on the experiences of community members, they deal with issues to which other residents can relate. This makes role model stories culturally sensitive and culturally appropriate.

Role model stories are framed using the Stages of Change Theory. Each story relates to changing one behavior, is written for one of the five stages of change, and uses one or more of the influencing factors. The purpose of the stories is to help people move toward consistent condom use. Agencies should develop stories that show how people move from not using condoms or using them only sometimes to using them all the time.

The role model stories should be developed into a colorful pamphlet or flyer that should fit in a pocket or purse. In addition, agencies developing their own role model stories or adapting existing ones should create an annual story plan. This plan outlines the number of stories an agency should put out every month, the stages and topic that will be dealt with and when each story will be distributed. Ideally, agencies should develop two new stories each month (a total of 24 stories a year).

If resources are limited, agencies should use existing stories that are available in the intervention package. Agencies can use them in their original form or adapt them so that they fit the community better.

Community Network: The community network is a group comprised of businesses, agencies and organization in the agencies' community. The primary function of the community network, another core element of RAPP, is to provide a place where role model stories are easily and widely available for their clients and customers. By making stories available to a large number of people, the community network provides an opportunity for community members to get HIV prevention messages.

The more businesses, agencies and organizations that are involved, the more agencies increase awareness of HIV and AIDS in the community. Agencies should have at least 25 members as part of the community network. Examples of businesses to recruit include nail and hair salons, barbershops, welfare offices, restaurants, banks, drug stores, newsstands, convenience stores, record stores, clothing shops, healthcare agencies, and schools.

Invitations for businesses and agencies to be involved in RAPP should be done in person, face-to-face, and should include a brief description of the project, community network member expectations, and a determination of the members' level of support for the project. Members of the community network should be sent at least two letters each year to say thanks for their support of RAPP and to report on the project's activities and accomplishments to keep them involved. Information about community networking activities should be recorded on the RAPP Activity Form.

Small-Group Activities: The small-group activities are another core element of RAPP and give people an opportunity to learn about HIV prevention. The outreach specialist and the peer volunteers should organize two kinds of small group activities: safer sex programs and HIV informational presentations.

Safer sex presentations are usually hosted by people in their homes, but can also take place in other settings, such as community centers, wherever people feel comfortable. The agency outreach specialist or peer volunteers should recruit residents from the community to host the party and invite six or eight of their friends over to play educational games, win prizes and learn about HIV prevention. The outreach specialist directs the activities. Peer volunteers may also host, help with, and lead safer sex presentations, which should last about one and a half hours. The host should be given an incentive in private such as a gift certificate. Information about the party should be recorded on the RAPP Activity Form.

HIV presentations provide a more formal group setting where people can learn about how HIV is spread and prevention strategies. The agency outreach specialist should conduct these presentations for the staff of local agencies, businesses and organizations that are apart of the community network as well as non-members. The presentations should last about one hour, with an optional follow-up session.

RESOURCE REQUIREMENTS

RAPP has 5 core elements that, when used together, can help people change their behavior. Once the project is fully up and running, the outreach activities connected with each of these elements should be going on at the same time. To be sure that this happens, these activities need to be coordinated in the field by one or more persons who also has outreach responsibilities. This person is the paid outreach specialist, whose role is vital to the success of the project. Agencies should hire or bring the outreach specialist onto the project as soon as possible after deciding to implement RAPP. The outreach specialist has major responsibilities during both the pre-implementation and implementation phases of the project. During the pre-implementation phase, the outreach specialist is responsible for conducting the community needs assessment that includes recruiting people for the focus groups and key participant interviews and identifying

volunteers for the peer network and the community network. After the community assessment phase is complete, the outreach specialist is responsible for the following: (1) conducting outreach, (2) scheduling peer network activity; (3) overseeing and tracking peer network activity; (5) training volunteers; (6) writing new role model stories; (7) conducting community networking; (8) facilitating safer sex parties; and (9) monitoring and record keeping. Agencies should consider the size of the community to be served, epidemiological data on HIV incidence rates and AIDS cases, and services available in their community when determining the number of outreach specialists needed for RAPP.

RECRUITMENT

Peer Volunteers: Conducting community outreach and small group activities using peer volunteers is a major function of the RAPP intervention. RAPP takes advantage of the power of peers to influence others by using them to encourage people to adopt new ideas about condom use and safer sex. Key characteristics of peer volunteers are that they like to talk to people on the street and are comfortable discussing HIV and other sensitive topics. The peer network should include persons of different ages, gender, and race based on the community that is being served. Members of the community can be recruited to join the peer network in the following ways:

- Active recruitment by the outreach specialist
- Volunteers of the network can invite their friends to join
- Post flyers and send out formal invitations
- Referrals from community based organizations, healthcare providers, homeless shelters, religious institutions, schools and other agencies

Role Models: RAPP role model stories are based on the real life experiences of people in the community and are written in the words of the people who tell them. Key characteristics of role models are that they use condoms consistently, or are in the process of making changes toward using condoms consistently, can describe experiences they have had trying to use condoms, and can explain how and why they have changed their behavior. Ways to recruit role model stories include:

- Solicit stories from peer volunteers
- Advertise on the back of the role model stories handed out by peer volunteers
- Post flyers in the community
- Recruit people who come to safer sex parties to tell their stories
- Referrals from community based organizations, healthcare providers, homeless shelters, religious institutions, schools and other agencies

Local Community Businesses: Obtaining program support from community organizations and businesses is also an important function of RAPP. Peer volunteers and the outreach specialist can recruit community network members from businesses and agencies that they use and places where their friends and family visit. Invitations to be involved should be conducted in person.

Incentives can be used to effectively enhance retention of volunteers in the peer network, recruitment of role models and participation in the community network. For example, gift certificates, monetary incentives, and food can be used as token of appreciation.

PHYSICAL SETTING CHARACTERISTICS

The intervention needs a place to hold trainings and staff meetings. Ideally the place should have comfortable seating for having discussions. Staff meetings can be held in the CBO's office space. Agencies implementing RAPP should choose a training location that is easily accessible from public transportation routes. The recruitment and risk reduction conversations take place in community venues where the target population lives, works, and socializes.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement RAPP the following policies and procedures should be in place to protect clients, the agency, and staff:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data, behavioral and clinical surveillance, and the state or local HIV prevention plan created with input from the state or local community planning group(s).

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Linkage of Services: Recruitment and health education and risk reduction must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of

Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: Agencies conducting recruitment, outreach, and health education and risk reduction, must establish a code of conduct. This code should include, but not be limited to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

For RAPP to work, all five core elements must be implemented together. Quality assurance activities allow agencies to track and document how RAPP was implemented and allow for changes to be made when necessary to meet RAPP outcomes. Quality assurance activities for both agency staff and volunteers should be in place when implementing RAPP.

RAPP Outreach Specialists: RAPP outreach specialists should have extensive knowledge of HIV transmission and statistics in their local jurisdictions as well as national statistics. Outreach specialists should reflect the target population in race, gender and age and will be expected to deliver the information in a non-threatening and culturally relevant manner.

RAPP Training: Peer Network Training - During the beginning of the RAPP intervention, the outreach specialist and peer volunteers should be trained by a professional who is strongly familiar with the curriculum. Later training sessions can be conducted by the outreach specialist using the materials in the RAPP Training Manual. Volunteers should have this training, followed by experience in doing peer networking before they participate in the stage-based encounter training.

Role Model Stories Training: This training should first be conducted by a trainer who is familiar with the application of stages of change theory and who has experience in conducting interviews. Subsequent training sessions can be conducted by the outreach specialist or agency staff. Additional one-on-one training may be needed.

Staged-Based Encounters Training (Two Days): This training should be conducted by the outreach specialist or agency staff. Participants of this training should have attended the one-day training for the peer network. The first day of this training should focus on identifying stages of change and the second day should concentrate on identifying and using influencing factors.

The two sessions should not be held more than one week apart. The training should be conducted with small groups of six to eight trainees. Frequent review and periodic re-training sessions with peer volunteers may be necessary.

For all RAPP Training: Quality assurance activities can include direct observation and review of training conducted by the outreach specialist. The review could focus on the quality (or adherence to the fidelity) of the training delivered, and responsiveness and openness of the volunteers to the outreach facilitator. The outreach specialist should collect all evaluation forms following the training and ensure confidentiality of the peer volunteers. In addition, outreach specialists should ensure that all participants are actively participating in the training activities. Monthly meetings with supervisors to discuss progress and/or opportunities for change are encouraged.

RAPP Outreach Activities: All RAPP outreach activities should be recorded on the RAPP Activity Reporting Form provided in the RAPP implementation package. The RAPP Activity Form allows agencies to track RAPP activities (core elements) that are implemented to ensure the intervention is being implemented as intended by the original researchers: The forms monitor the following:

- Who has been contacted, when, where and the outcome.
- The number and types of activities being conducted
- The type of persons being reached (by gender, age, risks)
- The number and type of referrals being made
- The supply of role model stories at drop sites.
- The number of safer sex parties and HIV presentations conducted

Keeping these records will help agencies monitor and assess how each RAPP core element is being implemented in the community.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **IA-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.

- **I.B-** The proportion of person who access counseling and testing from each of the following interventions: individual level interventions and group level interventions.
- **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
- **V.A -** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

¹Prochaska JO, DiClemente CC. (1983). Stages and processes of self-change of smoking: toward an integrative model of change. *Journal of Consulting Clinical Psychology*, 51, 390-395.

²Prochaska J, DiClemente CC. (1985). Common processes of self-change in smoking, weight control and psychological distress. IN S. Shiffman and TA Willis, eds. *Coping and Substance Abuse*. New York: Academic Press.

³Rogers EM. (1995). *Diffusion of Innovations* (4th ed.). New York: Free Press.

⁴Bandura A. (1977). *Social Learning Theory*. Englewood, N.J: Prentice-Hall.

⁵Adams J, Weissfeld L, Lauby J, Stark M. (1998). Effects on teenage women of a community-level HIV prevention intervention. Paper presented at 126 Annual Meeting of American Public Health Association, Washington, D.C.

⁶Person B, Cotton D. (1998). A model of community mobilization for the prevention of HIV in women and infants. *Public Health Reports*, 3 (suppl. 1), 89-98.

⁷Smith P, Person B, Adam J. (1998). Women who trade sex: results from a community intervention trial. Presented at the International Conference on AIDS, 1998.

⁸Terry M, Liebman J, Person B, Bond L, Dillard-Smith C, Tunstall C. (199?). The women and infants demonstration project: an integrated approach to AIDS prevention and research. *AIDS Education and Prevention*, 11(2):107-21.

⁹Lauby JL, Smith PJ, Stark M, Person B, Adams J. (2000) A community-level prevention intervention for inner city women: Results of the Women and Infants Demonstration Projects. *American Journal of Public Health* 90(2), 216-222.

Krueger RA. (1988). *Focus groups: A practical guide for applied research*. Sage Publications: Newbury Park, CA.

Morgan DL, Krueger RA. (1998). *The focus group kit*. Sage Publications: Thousand Oaks, CA.

For more information on receiving technical assistance or training on this intervention, please visit www.effectiveinterventions.org.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF SAFETY COUNTS

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF SAFETY COUNTS

Safety Counts is a cognitive-behavioral intervention to reduce HIV risks among active drug users and specifically targets active crack cocaine and injection drug users who are at very high risk for HIV/STD infection.¹ An important component of Safety Counts is recruitment, used to link clients to counseling, testing and referral, prevention and treatment services, care and other support services. Safety Counts is used with both HIV positive and HIV negative clients. This intervention has been packaged by CDC's Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

The primary objective of the intervention is to reduce HIV transmission among intravenous drug users (IDUs) and crack users who are not in treatment. The program also strives to increase the understanding of drug use patterns in relation to HIV infection risk as well as monitor HIV seroprevalence among drug users. The program consists of seven sessions held over four months: two group sessions, one individual counseling session, two (or more) group social events, and two (or more) follow-up contacts. The intervention uses incentives to encourage participation. Safety Counts also utilizes structured and unstructured psychoeducational activities in individual and group sessions.

The intervention incorporates social modeling, social support, and modified behavioral contracting. *Safety Counts* clients design and manage their own personal HIV risk-reduction plan with the support and guidance of counselors and outreach staff. This allows clients to recognize how their own behaviors may put them at risk for HIV, hepatitis C, other blood borne and sexually transmitted diseases; figure out for themselves what they can reasonably do to reduce their risk for HIV and hepatitis C; take ownership of their personal risk-reduction goals; and develop and manage solid plans for achieving those goals.

By engaging the client in group and individual sessions, *Safety Counts* helps form a partnership between the client and agency staff. This client-centered approach not only assists in reducing HIV risk behaviors and infection of clients, but also can have other benefits including reductions in drug use and increased entry into drug treatment for clients and their peers.

Research showed that participants in the intervention group were more likely to report an increase in condom use at follow-up (5-9 months after enrollment) compared to those in the

comparison group. Participants in the intervention group compared to the comparison group also reported they had stopped using crack, stopped injecting drugs, had reduced injection drug use, and fewer crack users tested positive for cocaine at follow up.¹

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Safety Counts has 4 core elements:

- 1) Two group sessions (identify client's HIV risks and current stage of change, hear risk-reduction success stories, set personal goal and identify first step to reduce HIV risk).
- 2) One individual counseling session (discuss/refine risk-reduction goal, assess client's needs and provide indicated referrals to C&T and medical/social services).
- 3) Two (or more) group social events (share meal and socialize, participate in planned HIV-related risk-reduction activities, receive reinforcement for personal risk reduction).
- 4) Two (or more) follow-up contacts (review client's progress in achieving risk-reduction goal, discuss barriers encountered, identify concrete next step and discuss possible barriers/solution, make referrals to C&T, and medical/social services).

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. Key characteristics of Safety Counts are:

- The content of group social event must contain a planned, HIV-related risk-reduction component but the activity can be educational games or workshops, roundtables or featured speakers
- The video of risk-reduction success stories, provided in the Safety Counts kit, is a copy of the one used in the original intervention showing how local drug users were able to successfully adopt sex- and drug-related risk-reduction strategies. Agencies implementing Safety Counts are strongly encouraged to make their own videos using individuals from their local communities to increase the authenticity of the risk-reduction success stories. Alternatively, agencies may choose to produce audio tapes or written stories, or arrange for live testimonials describing personal risk-reduction successes. Live testimonials are considered to be the least desirable mechanism because of their uncontrolled nature
- The length of the individual contracting session can be increased from the recommended time of 15-30 minutes

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the conduct of the intervention. Procedures for implementing Safety Counts follow below:

As a result of the activities in this intervention, voluntary counseling and testing is offered to clients. If the implementing agency already offers counseling and testing, then this intervention fits in well with these services. If not, provide active referrals to agencies that do provide counseling and testing. Although HIV testing is not required before attending the first intervention session, clients who have not recently been tested should be encouraged to get tested and learn their status as soon as possible.

Peer recruitment and outreach is an important component of Safety Counts. Clients who participate in the intervention recruit their peers into the group sessions. Once a peer enrolls in the Safety Counts program, they are encouraged to seek counseling and testing for HIV, hepatitis C and other infectious diseases as soon as possible, preferably on site. Staff also refer clients to prevention and treatment services, drug treatment services, shelter and other social, medical and support services.

General tips on the procedures for implementing Safety Counts include:

- Meeting space that is comfortable and inviting and may allow participants to smoke
- Intervention times and locations that are consistent (i.e., same time and place), convenient and don't conflict with participants' other responsibilities or needs
- Intervention sessions (especially groups and socials) that are lively and developed with plenty of input from participants themselves
- Programming that creates a dependable environment of trust and respect
- Programming that strictly maintains confidentiality
- Programming that includes the capacity to refer participants to other services (domestic abuse agencies, rape counseling, and mental health)

Specific guidance on procedures for implementing Safety Counts includes:

Group Sessions 1 and 2 (One Session Each)

The group sessions use a stages-of-change framework to help clients identify their personal stage of change. They are an opportunity for clients to talk with peers and agency staff about risk behaviors and prevention methods. The sessions establish that personal risk reduction is relevant, needed, and achievable. Clients think about how risk behaviors apply to them and begin a process to reduce a particular risk. Within the group sessions, the clients set a personal goal for reducing HIV risk and decide on a first step toward meeting that goal.

Individual Behavioral Counseling (One Session Minimum)

The individual behavioral counseling session, which is conducted after the group sessions, gives clients an opportunity to reflect on their personal risk-reduction goals and barriers to goal achievement. Clients work with counselors to revise their goals if they are unrealistic or too

difficult to achieve, and to determine more achievable, smaller steps toward risk reduction. They may also find that the goals they set were easily achievable, and be ready to set more challenging goals. In either case, individual sessions allow for the intimacy of discussing risk-taking behavior in more detail in confidentiality. This session also provides an opportunity to build rapport between the counselor—who acts as a supporter—and the client. Finally, the individual session is an opportunity for assessing a client's needs and ensuring referrals for medical and support services.

Social Events (Two Minimum)

The *Safety Counts* intervention calls for clients to attend a minimum of two social events following their participation in the group session. The social events must have a planned HIV-related risk reduction activity such as a game, workshop or speaker. The socials, which are typically offered on a monthly basis, provide an opportunity to strengthen clients' relationships to the program, to agency staff, and to peers. In a less formal setting, with a meal provided, clients are given support for their progress in achieving personal risk-reduction goals. Clients are also encouraged to invite friends and family members. These socials can help motivate clients to complete the full seven-session intervention.

Follow-up Contacts (Two Minimum)

Outreach workers conduct at least two supportive follow-up contacts with clients subsequent to the individual counseling session. These encounters are structured and planned in advance with input from other agency staff who have worked with the client. Follow-up encounters may be conducted in the office, on the street, in the home, or elsewhere in the community. The purpose is to review risk-reduction progress made by the client and to encourage achievement of the client's personal risk-reduction goal. Outreach staff reinforce the client's risk-reduction efforts, assess his or her progress, and offer strategies to overcome reported barriers. At this time, referrals for social, medical, drug treatment, shelter, and other support services are again offered as needed.

RESOURCE REQUIREMENTS

Like most interventions of its kind, the effectiveness of *Safety Counts* depends on the people who implement it. Team members must be sensitive, skilled, and knowledgeable about the drug-using culture and its various populations. Besides the executive director of the implementing agency, *Safety Counts* requires at least four team members:

- One program manager
- Two outreach workers, working as a pair in an outreach team
- One behavioral counselor who can facilitate group and individual sessions and socials

Resources permitting, more than two outreach workers and, preferably, more than one counselor should be used for the intervention. The counselor does not need to be a licensed professional; a trained paraprofessional can work very well. The more outreach teams put into the field, the

greater numbers of drug users will be accommodated through the *Safety Counts* intervention. Some basic administrative support is helpful, if available. Management of the intervention will be easier if all team members are responsible to a single organization, but there may be cases where agencies pool human resources and partner with other agencies.

In addition to the intervention team, other program resources that are necessary to implement *Safety Counts* include:

Transportation for Clients and Outreach Workers: Transportation could include the organization's van, another organization's van used by agreement, personal cars, and public transportation. In some localities, use of a van for other than personal purposes to transport multiple individuals requires the driver to be a licensed chauffeur. Use of personal cars requires the driver to assume liability for any accidents. Adequate and up-to-date insurance is required for all means of transportation (other than public).

Outreach Materials: These can include anything already used in outreach activities to active drug users or new materials developed especially for *Safety Counts*.

Collaborative Partnerships with Other Organizations: These include partnerships with other organizations to provide component parts of *Safety Counts* if all components cannot be delivered by the primary agency.

Incentives for Clients: These are the “perks” that will help retain clients in *Safety Counts* activities. Incentives such as cash and food should be used whenever possible to recruit clients and maintain their participation in the program. Other types of incentives include: meals at meetings, raffles (e.g., enroll at recruitment with proviso that to win, participant must remain in the interventions), condoms, feminine hygiene products, free or reduced-fee childcare, free or reduced-fee transportation to or from meetings, food and clothing vouchers, hot showers or a place to clean up. Ideally, a combination of the incentives listed above will result in recruitment and retention of participants. As time goes on, participants may identify other incentives that may be more desirable.

A Referral Network in Place for Client Needs that the Organization Cannot Address, Especially HIV Counseling and Testing Services: This may be a network already in place or a new network to be developed. Agencies must be certain that they have specific referral information for clients; i.e., the name of the appropriate staff person at the other agency and that the agency provides high-quality services. Staff should follow up with the client and the other agency about whether action occurred on the referral.

The cost of implementing *Safety Counts* will vary based on regional and local differences in salaries, transportation costs, the cost of various goods and services, and other factors. However, the cost of *Safety Counts* can be significantly reduced if supplies (condoms), services (food preparation) and incentives (food vouchers) are donated rather than purchased. Local suppliers, caterers, grocers, food banks and restaurants, movie theatres, clothing outlets, drugstores, museums, media outlets, public transportation authorities, taxi companies, and other merchants should all be approached for donations in the preparation phase of program planning.

RECRUITMENT

The recruitment activity is an important component of *Safety Counts*. Primary responsibility for recruiting active drug users into the intervention program rests with the agency's paid outreach staff. Most agencies will be able to use their current outreach workers, with established relationships and linkages to drug-using individuals in the local community, to promote *Safety Counts* and develop interest in the program among members of the target population. It is essential that outreach workers for *Safety Counts* be completely familiar with the local drug-using community, and it is preferable that they be recovering drug users. Agencies that do not have significant experience outreaching to active drug users are encouraged, prior to program implementation, to form a peer advisory panel composed of indigenous current and/or former drug users to guide initial recruitment efforts and provide advice concerning effective participation incentives. (See "Resource Requirements" for a discussion of possible incentives.)

During the recruitment process, outreach workers not only promote the *Safety Counts* program to potential participants, but they are also encouraged to perform a brief assessment of individual needs for medical and social services, including C&T and drug treatment, and to make specific referrals as indicated. Fold-over handout cards describing services in the local area are highly recommended. The needs assessment and referral component of *Safety Counts* recruitment is considered a key benefit of the program.

PHYSICAL SETTING CHARACTERISTICS

Space for Group Meetings: This space should be reliably available when needed. The space should be flexible; i.e., large enough to accommodate group activities such as icebreakers as well as comfortable seating arrangements for large- and small-group activities. Ideally, the group meeting space would come equipped with a VCR, television monitor, and newsprint easels. If these items don't come with the space, they will need to be obtained elsewhere.

Space for Private, One-on-One Counseling Sessions: This space must be a room with a door. Open cubicles or other venues that are not completely private are not appropriate. The private space should have comfortable seating for counselor and client.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement *Safety Counts*, the following policies and procedures should be in place to protect participants, and the agency:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data, behavioral and clinical surveillance, and the state or local HIV prevention plan created with input from the state or local community planning group(s).

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Linkage of Services: Recruitment and health education and risk reduction must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: Agencies conducting recruitment, outreach, and health education and risk reduction, must established a code of conduct. This code should include, but not be limited to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Successful implementation of Safety Counts requires that team members possess the following attributes:

- Familiarity with the process and logistics of drug use.
- Familiarity with the drug-using culture and its various populations.
- Familiarity with HIV and its prevention.
- Good verbal communication skills.
- Personal characteristics that facilitate communication (e.g., nonjudgmental attitudes, active listener, friendly and outgoing, trustworthy).

A strong component of maintaining program quality is preparing a plan to implement Safety Counts. Developing a comprehensive implementation plan will facilitate understanding and “buy-in” from staff and increase the likelihood the intervention runs smoothly.

Quality assurance on this intervention also requires that someone at the agency will provide hands-on leadership and guidance for the intervention—from preparation through institutionalization. A decision maker is needed in the agency who will provide higher-level support, including securing resources and advocating for Safety Counts, from preparation to institutionalization.

Throughout implementation, it is necessary to determine whether staff is maintaining fidelity to the content of the four core elements: (1) two group workshops; (2) one individual counseling session; (3) two (or more) group social events; (4) two (or more) follow-up contacts. It is also necessary to identify and address any issues to assure the intervention is meeting the needs of agency clients and staff. Staff who are implementing Safety Counts can develop their own Quality Assurance Checklist to help staff identify, discuss and solve problems in successfully implementing the intervention.

The Safety Counts implementation manual provides guidance on developing a plan for program monitoring. The implementation manual provides two suggested forms: a worksheet that supports process evaluation for the program overall and an instrument that measures individual outcomes.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC’s requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:

- **I.A-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.
- **I.B-** The proportion of person who access counseling and testing from each of the following interventions: individual level interventions and group level interventions.
- **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
- **V.A -** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

¹ Rhodes F, Wood MM, Hershberger S. (2000). A cognitive-behavioral intervention to reduce HIV risks among active drug users. In *Staying negative in a positive world: HIV prevention strategies that work* (pp. 113-124). Sacramento: California Department of Health Services, Office of AIDS.

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Wood,MM, Rhodes F. (1998 April). A cognitive-behavioral intervention to reduce HIV risks among active drug users: Implementation issues. Paper presented at the *Staying Negative in a Positive World: HIV Prevention Strategies That Work Conference*, Los Angeles.

For more information on the Safety Counts intervention, training and technical assistance, or to get your name on a list for a future training, please go to the website:

<http://www.effectiveinterventions.org>.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF THE SISTA PROJECT— A PEER LED PROGRAM TO PREVENT HIV INFECTION AMONG AFRICAN AMERICAN WOMEN

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF SISTA

The SISTA Project—or Sisters Informing Sisters About Topics on AIDS -- is a social skills training intervention aimed at reducing HIV sexual risk behavior among African American women at highest risk.¹⁻³ It is composed of five two-hour sessions delivered by peer facilitators in a community based setting. The sessions are gender – and culturally- relevant and include behavioral skills practice, group discussions, lectures, role play, a prevention video, and take home exercises. The five sessions that generate these discussions and activities include Ethnic/Gender Pride; HIV/AIDS Education; Self Assertiveness Skills Training; Behavioral Skills Management; and Coping. This intervention has been packaged by CDC’s Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

SISTA applies both the Social Cognitive Theory and the theory of gender and power. According to the Social Cognitive Theory, people need information (HIV risk-information), training in social and behavioral skills, and knowledge of norms to apply risk-reduction strategies. A change in behavior is dependent upon self-efficacy, self confidence, and outcome expectations.

The theory of gender and power is a social structural theory that accounts for gender-based power differences in male-female relationships. It examines, by gender, the division of labor and the distribution of power and authority within relationships and gender-based definitions of sexually appropriate conduct. In addition, the theory considers the impact of a woman’s willingness to adopt and maintain sexual risk-reduction strategies within heterosexual relationships as it pertains to her lack of power, her commitment to the relationship and her role in the relationship.

The study was originally implemented with 128 heterosexual women. Results indicated that a social skills training that is delivered in a community setting can positively affect condom use. Specifically, women in the experimental condition reported more condom use than women in the control condition.¹

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's or strategy's intent and design that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. SISTA has 7 core elements which include:

- 1) Small group sessions to discuss the session objectives, address the challenges and joys of being an African American woman, model skills development and role play women's skills acquisition.
- 2) Use of a skilled facilitator to implement the group sessions because the success of the SISTA Program depends on the skill of the facilitator.
- 3) Use of cultural and gender appropriate materials to acknowledge pride, enhance self worth in being an African American woman (e.g., use of poetry, artwork by African American women).
- 4) Training of women in sexual assertion skills so that they can both demonstrate care for partners and negotiate safe behaviors.
- 5) Teaching women proper condom use skills. SISTA is designed to foster positive attitudes and norms towards consistent condom use and provide women the appropriate instruction for placing condoms on their partner.
- 6) Discussions of the cultural and gender triggers that may make it challenging to negotiate safer sex.
- 7) Emphasis on the importance of the partner's involvement in safer sex. The homework activities that are included in the SISTA Project are designed to involve the male partner.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be adapted or tailored to meet the needs of the target population in different agencies and ensure cultural appropriateness of the strategy. SISTA has the following key characteristics:

- Flexibility to be tailored for different populations of African American women, for example, women in substance abuse treatment facilities, incarcerated women, women residing in shelters, and sex workers.
- Passion, such that the facilitators can deliver the intervention with conviction and purpose.
- Cultural competency, in that it was developed by African American women and for African American women.

- Broad content that includes discussions not only about HIV prevention, but also about relationships, dating, and sexual health.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for implementing the SISTA project follow.

The SISTA Project consists of:

- Five once-a-week sessions that are two hours each
- Two booster sessions administered two and four months after the project is completed, also two hours in length. These booster sessions are designed to provide an opportunity for the program participants to ask further questions and/or provide peer support
- A graduation party and a Certificate of Accomplishment for each of the participants after completion of the second booster session

Each of the sessions has a specific goal and objectives. The goals and activities of each of the sessions follow:

Session 1-Ethnic/Gender Pride:

Goal: Generate a discussion about being African-American and female, having pride in oneself, and valuing oneself.

During the first session, the facilitators will:

- Distribute an opening poem that will be read with and/or to the women
- Introduce themselves to the women, introduce the intervention to the women and introduce the women to each other
- Encourage the women to develop ground rules and expectations
- Facilitate a discussion about the positive qualities of black women and how they can be used as a source of strength and pride; conduct a discussion on values, requesting the women to prioritize their personal values
- Encourage the women to complete a simple homework exercise
- Distribute anonymous evaluation forms to assess the first session
- Read a closing poem with and/or to the women and recite the SISTA motto with the women

Session 2-HIV/AIDS Education:

Goal: Provide factual and statistical information on HIV/AIDS and other sexually transmitted diseases (STDs), correct misconceptions about HIV/AIDS, and discuss the importance of protecting oneself.

During session 2, the facilitators will:

- Distribute a copy of a poem that will be read with and/or to the women
- Review ground rules and expectations
- Review the key concepts of session 1 and discuss the homework exercise from day 1
- Distribute information and handouts on HIV/AIDS and initiate discussions about the information
- Engage the women in a Card Swap game to demonstrate how people get HIV and spread it to other people
- Present a 30 minute video and discuss
- Distribute homework assignments
- Distribute anonymous evaluation forms to assess the second session
- Recite the SISTA motto with the women.

Session 3-Assertiveness Skills Training:

Goal: Teach the distinction among assertive, aggressive and non-assertive behaviors and teach skills to initiate assertive qualities.

During the third session, the facilitator will:

- Distribute a copy of a poem that will be read with and/or to the women
- Review the key concepts of session 2 and discuss the homework exercise from day 2
- Facilitate a discussion on the difference between assertion and aggression
- Distribute a handout on various realistic situations and ask the women to provide examples and consequences of assertive, aggressive and non- assertive responses to the situations; discuss steps in the decision making process
- Distribute homework assignments will be distributed
- Distribute anonymous evaluation forms to assess the third session
- Read the closing poem with and/or to the women and recite the SISTA motto with the women

Session 4-Behavioral Self-Management:

Goal: Decrease participants' anxiety about condom use, demonstrate and role-play how to use condoms and discuss reasons that women do not insist upon using condoms.

During session 4, the facilitator will:

- Distribute a copy of a poem that will be read with and/or to the women
- Review the key concepts of session 3 and discuss the homework exercise from day 3
- Facilitate a discussion on why people do not use condoms and develop a strategy for overcoming these stated obstacles
- Distribute condom packets and lubricant
- Engage the women in a condom-card line-up activity to assess their knowledge of putting on a condom
- Demonstrate how to put on a condom

- Role play negotiation exercises
- Disseminate homework assignments
- Distribute anonymous evaluation forms
- Read the closing poem with and/or to the women and recite the SISTA motto with the women

Session 5-Coping Skills:

Goal: Initiate discussion about coping with life experiences -- including the link between alcohol and AIDS, coping with alcohol and sex, and coping with negative responses. This session also serves as a review of the previous sessions.

During the fifth session, the facilitator will:

- Distribute a copy of a poem that will be read with and/or to the women
- Review the key concepts of session 4 and discuss the homework exercise from day 4
- Review the handouts from previous sessions
- Discuss what coping is and its relationship to alcohol
- Distribute a handout on coping situations
- Inform the group of the booster sessions
- Distribute Anonymous Evaluation forms
- Read the closing poem with and/or to the women and recite the SISTA motto with the women

Booster Sessions: The booster sessions offer participants the opportunity to ask questions, stimulate thinking/knowledge of lessons learned, and reinforce the importance of protecting oneself. The first booster session is held two months after the last session of the intervention. The facilitator will facilitate discussions on (1) how the intervention could be strengthened; (2) whether the participants are using their newly developed skills; and, (3) any challenges that the participants have encountered. In addition, participants will begin designing their graduation ceremony.

The second booster session is held four months after the intervention. Additional questions are answered and the graduation ceremony is held.

RESOURCE REQUIREMENTS

The SISTA intervention should be facilitated by two peer health educators (at least one full time employee). Peers should be of the same race/ethnicity and gender as the target population. The staff should be well versed on HIV transmission and methods for preventing HIV transmission and should have a non-judgmental attitude toward people living with HIV/AIDS. Partnering agencies, if any, should be identified as well as a location to conduct a group session with 10-12 women.

Prior to implementing the intervention the staff should thoroughly review all program materials, plans, and logistics. Specific materials and instructions are provided in the intervention kit. In addition, the staff should copy materials, purchase incentives (described below) and other materials necessary to implement the intervention. Staff should create a culturally sensitive atmosphere and should understand the participant's cultural heritage and institutional barriers. Staff-participant language and dialect matches should also be considered. This will enable the staff to understand how the clients relate to the world.

RECRUITMENT

To encourage participation, SISTA should be publicized as a program for African-American women developed by African-American women that discusses dating, relationships, healthy sexual practices, and works at improving women's ability to effectively communicate with sexual partners. SISTA is a behavioral change intervention targeting women at very high risk for HIV. Clients may be recruited from various venues, including shelters, juvenile court systems, bars, focus groups, jails/prisons, STD clinics or community organizations. Specific cultural needs should be addressed when finding a client population.

Agencies implementing SISTA should see the Procedural Guidance for Recruitment in this document for recruitment strategy options.

Incentives can be used to effectively enhance retention in the SISTA program. For example, bus tokens may be used to provide women with transportation to and from the sessions, childcare may be provided during the sessions. In addition, gift certificates, monetary incentives, and food are all used as positive reinforcements.

PHYSICAL SETTING AND CHARACTERISTICS

Agencies implementing SISTA should choose a location that is easily accessible from public transportation routes. The intervention sessions must be conducted in a secure location such that confidentiality of participants is maintained. It is important that sessions are not interrupted by distractions, such as people entering and exiting the room, or outside noise levels. The location should be able to accommodate 10-12 persons comfortably and privately. In addition, the agency should take into consideration the intervention activities, including role play and role demonstration.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement POL the following policies and procedures should be in place to protect clients, the agency, and the facilitators:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data,

behavioral and clinical surveillance, and the state or local HIV prevention plan created with input from the state or local community planning group(s).

Informed Consent: Agencies must have a consent form which carefully and clearly explains in accessible language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Legal/Ethical Policies: Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility if a client tests positive for HIV. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Linkage of Services: Recruitment and health education and risk reduction must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, or other Health Department/Community Based Organization prevention programs) if clients need additional assistance in decreasing risk behavior.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National*

Standards for Culturally and Linguistically Appropriate Services in Health Care which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: Agencies conducting recruitment, outreach, and health education and risk reduction, must establish a code of conduct. This code should include, but not be limited to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance (QA) activities for both providers and participants should be in place when implementing SISTA.

Provider: Facilitators of SISTA should have extensive knowledge of HIV transmission and statistics in their local jurisdictions as well as national statistics. Facilitators should reflect the target population in race and gender and will be expected to deliver the information in a non-threatening and culturally relevant manner. Agencies should have in place a mechanism to ensure all sessions and core elements, as described above, are implemented. QA activities can include direct observation and review of sessions by staff involved in the intervention. The review could focus on the quality (or adherence to the fidelity) of the sessions delivered, and the responsiveness and openness of the women to the facilitator. Facilitators should collect all evaluation forms following each session and ensure participant confidentiality. In addition, facilitators should ensure that all participants are actively participating in each of the sessions. Bi-monthly meetings with supervisors to discuss progress and/or opportunities for change are encouraged.

Participants: The participants' satisfaction with the intervention and their comfort should be assessed during each session. Evaluation forms are provided in the intervention box and should be disseminated during each session. In addition, agencies can develop their own forms to assess participant satisfaction.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.A-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.
 - **I.B-** The proportion of person who access counseling and testing from each of the following interventions: individual level interventions and group level interventions.
 - **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).
 - **III.B-** Proportion of persons at very high risk for HIV infection that completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
 - **V.A -** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

¹DiClemente RJ, Wingood GM. A Randomized controlled trial of an HIV sexual risk reduction intervention for young African American women. *The Journal of the American Medical Association*, 1995, 274(16), 1271-1276.

²Wingood GJ, DiClemente RJ. Partner influences and gender-related factors associated with noncondom use among young adult African American women. *American Journal of Community Psychology*, 1998, 26(1), 29-49.

³Wingood GM, DiClemente RJ. Application of the theory of gender and power to examine HIV-related exposures, risk factors, and effective interventions for women. *Health Education & Behavior*, 2000, 27(5), pages 539-565.

The SISTA Project intervention box was developed by Sociometrics. For more information on receiving training on this intervention, please visit www.effectiveinterventions.org.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF MANY MEN, MANY VOICES

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF MANY MEN, MANY VOICES

Many Men, Many Voices (MMMV) is a six- or seven-session, group level HIV/STD prevention intervention for gay and bisexual men of color adapted from the Behavioral Self-Management and Assertion Skills intervention¹ (now called Partners in Prevention) developed by the Center for AIDS Intervention Research (CAIR) in the Department of Psychiatry and Behavioral Medicine at the Medical College of Wisconsin. This intervention has been packaged by CDC's Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

The original model intervention was condensed from twelve sessions to six (with an optional seventh) but individual sessions were expanded from 90 minutes to 2-3 hours. It was adapted and tailored using the strategies outlined in the *Procedural Guidance*, to address behavioral influencing factors specific to gay men of color including cultural/social norms, and values and sexual relationship dynamics. The adaptation, tailoring and implementation of this intervention were done in partnership with Men of Color Health Awareness (MOCHA), People of Color in Crisis (POCC) and the Center for Health and Behavioral Training (CHBT).

Many Men Many Voices is designed to be facilitated by a peer in groups of 6-12 participants. The three hour sessions aim to foster positive self identity, educate participants about their HIV/AIDS risk and teach assertiveness skills. For participants who are unaware of their HIV status, the benefits of knowledge of serostatus should be addressed, and referral for counseling and testing should be provided when appropriate. The program utilizes behavioral skills practice, group discussions, role play and lectures in highly interactive sessions.

In the original Partners in Prevention intervention, gay men who participated reduced their frequency of unprotected anal intercourse and increased their use of condoms significantly more than men in the control condition.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are

derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. There are 5 core elements of MMMV:

- 1) Educate clients about HIV risk and sensitize to personal risk.
- 2) Develop risk reduction strategies.
- 3) Train in behavioral skills.
- 4) Train in sexual assertiveness.
- 5) Provide social support and relapse prevention.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. MMMV has the following key characteristics:

- Foster positive identity development for gay men of color by exploring the dual identity culture of gay men of color, addressing social and cultural norms within racial/ethnic communities, exploring positive and negative peer influences, setting self-standards and clarifying values
- Discuss sexual roles and risks, addressing knowledge of HIV transmission risk and exploring beliefs about those risks
- Address perceived personal risk and personal susceptibility for HIV infection as well as the perceived benefits and outcomes of remaining HIV negative
- Increase skills and self-efficacy for protective behaviors and intentions to engage in those behaviors
- Explore sexual relationship dynamics including power dynamics
- Address the importance of peer support and social influence on maintaining healthy behaviors

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for implementing MMMV follow.

Many Men, Many Voices is implemented by one or two group level facilitators who are trained in the specific content of each group session. The facilitators are responsible for coordinating all activities and organizing all aspects of the intervention. At least one of the facilitators must be a gay or bisexual male of color.

The intervention consists of educational materials for distribution which may be used to recruit persons at risk into the group. Outreach by project staff is also necessary to recruit gay/bisexual men of color into the intervention sessions. The intervention was not designed for heterosexual males and they should not be included in the sessions. Men of color who have sex with other

men but do not identify as “gay” or “bisexual” are appropriate for the intervention as long as they are willing to discuss the STD and HIV risks of male to male sexual behaviors and the risk reduction methods that constitute safer sex.

The original 12 session intervention¹ was tailored and condensed into the 6 sessions of Many Men, Many Voices. An optional seventh session may be added at the discretion of the group facilitators. The seven sessions address specific influencing factors in a purposeful sequence including:

- Session 1: The Dual Identity Culture of Gay Men of Color
- Session 2: HIV Prevention for Gay Men of Color – Sexual Roles and Risks
- Session 3: HIV Risk Assessment and Prevention Options
- Session 4: Intentions to Act and Capacity to Change
- Session 5: Partner Selection, Communication and Negotiation
- Session 6: Social Support and Problem Solving to Maintain Change
- Session 7 (optional): Building a Healthy Community

The original 75-90 minute sessions were tailored and expanded to 2-3 hour Many Men, Many Voices sessions. Sessions contain very little presentation of information, and instead are highly interactive and allow for the clients to gain knowledge experientially (for example, through the use of educational games, and other exercises). Through their formative evaluation, the agencies that adapted the intervention found that the African American gay/bisexual men that they served were more inclined to attend 7 sessions of 2-3 hours each rather than 12 sessions of 75-90 minutes. An agency may conduct its own formative evaluation to determine whether participation rates would increase or decrease relative to the number of sessions and the length of each session. Whether the agency chooses to conduct fewer sessions of longer length or to conduct more sessions of shorter length should be based on client needs and client convenience. The intervention may also be condensed into a weekend retreat format, covering the 18-21 hours of intervention materials over the course of a single weekend. The entire content of the sessions constitutes the core elements of this intervention and so the entire content must be covered to implement the intervention with fidelity.

RESOURCE REQUIREMENTS

The agency should hire at least one full-time group facilitator. A second facilitator can be hired at a full- or part-time level depending on the level of need in the community. Group facilitation skills are necessary and should be a consideration in hiring staff or in initial training of staff. Facilitators are responsible for all aspects of the program including recruitment, group facilitation, record keeping, quality assurance, and monitoring and evaluation. Therefore it is recommended that each group facilitator run no more than two concurrent groups. An administrative employee of the community based organization typically supervises the group facilitator(s).

In addition to staff of the intervention, materials that are needed to conduct the intervention include markers, easel charts and newsprint, a VCR and television, an overhead projector, masking tape, poster boards, and clothespins.

RECRUITMENT

The target population for Many Men Many Voices is gay and bisexual men of color. Recruitment into the intervention sessions will include outreach to venues where MSM of color can be reached. Printed materials may also be used to recruit MSM of color into the intervention. The group facilitators generally recruit participants, but clients may also be referred to the groups through other programs. It is best if the group facilitators interview potential group members prior to the first group to determine if the individual is appropriate for the group.

Agencies wishing to implement Many Men, Many Voices should review the Procedural Guidance for Recruitment in order to choose a recruitment strategy that will work in the setting in which they plan to implement MMMV.

PHYSICAL SETTING CHARACTERISTICS

Agencies implementing Many Men Many Voices should choose a location that is easily accessible from public transportation routes and is also in communities where young gay/bisexual men of color live, work and socialize. The groups are usually held at the CBO, but can be held in other locations. Ideally the space should have comfortable seating for discussions. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room, or outside noise levels.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement MMMV the following policies and procedures should be in place to protect participants, the agency, and the MMMV program team:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data, behavioral and clinical surveillance, and the state or local HIV prevention plan created with input from the state or local community planning group(s).

Informed Consent: Agencies must have a consent form which carefully and clearly explains in accessible language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Legal/Ethical Policies: Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility if a client tests positive for HIV. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Linkage of Services: Recruitment and health education and risk reduction must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, or other Health Department/Community Based Organization prevention programs) if clients need additional assistance in decreasing risk behavior.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: Agencies conducting recruitment, outreach, and health education and risk reduction, must established a code of conduct. This code should include, but not be limited to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance (QA) activities for both facilitators and participants should be in place when implementing MMMV:

Facilitator: Training for facilitators should address the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practice of mock intervention sessions. Agencies should have in place a mechanism to ensure that all session protocols are followed as written. QA activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on adherence to session content, use of interactive techniques; accessibility and responsiveness to expressed participant needs; and important process elements (e.g., time allocation, clarity of presentation). Selected intervention record reviews should focus on assuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at the final session of each module. Process monitoring systems should also track the number of sessions each participant attends, as well as reasons for non-attendance.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **IA-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.

- **I.B-** The proportion of person who access counseling and testing from each of the following interventions: individual level interventions and group level interventions.
- **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).
- **III.B-** Proportion of persons at very high risk for HIV infection that completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
- **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
- **V.A -** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

¹Kelly JA, St. Lawrence JS, Hood HV, Brasfield TL. (1989). Behavioral intervention to reduce AIDS risk activities. *Journal of Consulting and Clinical Psychology*, 57(1), pp. 60-67.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF COMMUNITY PROMISE

CBO PROGRAM ANNOUNCEMENT RFP 2003-N-00895
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF COMMUNITY PROMISE

Community PROMISE is a community-level STD/HIV prevention intervention that relies on the outreach work of peer advocates from the target community to deliver role model stories to members of the target population. Peer outreach is the main vehicle of delivery for the intervention, and the work of peer advocates is one of the core elements of the intervention. Community PROMISE is an acronym for Peers Reaching Out and Modeling Intervention Strategies. This intervention has been packaged by CDC's Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

Community PROMISE is adapted by each community and thus can target a wide variety of high risk populations, including injection drug users, their sex partners, people living with HIV, sex workers, non-gay identified men who have sex with men, high risk youth, and others. Community PROMISE has used role model stories to disseminate many types of messages that address the prevention needs of these different populations. The prevention messages in role model stories can be used to encourage peers to seek HIV counseling and testing services, partner counseling and referral services, and other prevention and treatment services.

The impact of Community PROMISE extends beyond the individuals who are involved in the intervention, changing behavior within a community by influencing attitudes, beliefs and norms through social networks within those communities. Community PROMISE is grounded in several behavioral theories, including the Stages of Change model.

Results from a 3-year cross-sectional study found Community PROMISE to be effective in five cities across the United States in promoting community-wide progress toward consistent HIV risk reduction. PROMISE affected movement toward consistent condom use with main and non-main partners and increased condom carrying among those in the intervention compared to comparison communities. In addition, individuals in the intervention had higher stage-of-change scores for condom and bleach use than those in the comparison group.^{1,2}

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Community PROMISE has 3 core elements:

- 1) **Community Identification Process:** Community identification is a formative research process focused on intervention development and designed to assist in identifying, prioritizing, accessing, and understanding groups targeted for intervention.
- 2) **Role Model Stories:** Role model stories are the “heart” of printed materials distributed throughout the community. They are personal accounts from individuals in the target population who have already made some risk-reduction behavior change.
- 3) **Peer Advocates:** Peer advocates are recruited and trained to disseminate role model stories.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. Key characteristics of Community PROMISE are:

- Discussing the appropriateness of the intervention and necessary program resources with stakeholders
- Networking with other agencies and community organizations to avoid duplicating efforts, to elicit support and cooperation, and to find referral sources
- Forming a community advisory board to foster community commitment to the project and to develop a plan for accessing at-risk community members
- Assessing the community to develop a clear understanding of the composition of the target population, to identify specific risk behaviors and the contexts in which they occur, to discover the meaning of risk practices to the population, and to learn what members of the population believe are appropriate and relevant risk-reduction messages
- Reviewing recent epidemiologic data
- Interviewing agency staff and members of at-risk populations
- Conducting community mapping and focus groups specifically for this assessment
- Identifying the most prevalent stage(s) of change among at-risk populations for various risk reduction practices
- Assembling the information and preparing a comprehensive report
- Using community assessment information to decide on a specific target risk-reduction behavior
- Recruiting members of the target population (e.g., current or former commercial sex workers) or credible outreach staff to be peer advocates

- Training peer advocates for 1 to 3 hours on program goals, HIV/AIDS, and use of role model stories
- Establishing a system for maintaining advocates' commitment
- Recruiting, screening, and interviewing community members who are members of the local target population and who are performing behaviors to avoid HIV; their safer sex decisions will form the basis for role model stories
- Writing and locally pre-testing brief (400 words or less) role-model stories to address the target population's targeted risk behavior based on examples available in the intervention kit.
- Including in role-model stories relevant and realistic circumstances, the person's initial stage of change, motivator, action step, resolved challenge, and positive consequences of making a particular behavior change
- Having peer advocates distribute stage-appropriate stories to their peers and reinforce the stories' messages in conversation
- Having peer advocates distribute condoms, lubricants, and/or bleach kits along with the role-model stories
- Having each advocate distribute role model stories and risk reduction supplies to 10 to 20 peers each week

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention.

Procedures for implementing Community PROMISE follow below:

Community Identification (CID) Process

Community identification is a formative research process focused on intervention development and designed to assist in identifying, prioritizing, accessing, and understanding groups targeted for intervention. Methods used to collect information include focus groups, key informant and gatekeeper interviews, community observation, and surveys of internal staff and external sources. Community identification helps to accurately define problems and identify solutions, reveals community norms and the community's stage(s) of change, helps develop trust, informs intervention approaches, and identifies peers who can be involved in the intervention outreach. A key component of community identification is mobilizing the community to support and participate in the intervention. For example, local shops can make available prevention and other materials related to the intervention.

In preparation for the CID process, agencies identify which formative evaluation methods to use and develop or adapt the necessary instruments, such as interviews, community observation protocol, focus group script and materials, informed consent, and field safety guidelines. Staff are hired or current staff trained to conduct the formative evaluation process. The staff debriefs on the findings and makes decisions and develops implementation plan accordingly. Staff outreach workers play a role in recruiting members of the target population for in-depth interviews, identifying possible role models to be used in role model stories and are, in general, liaisons between peer volunteers, members of the target population and other agency staff. The primary duty of outreach staff is to train and supervise the peer volunteers.

Role Model Stories (RMS)

Role model stories comprise the “heart” of printed materials distributed throughout the community. They are personal accounts from individuals in the target population who have already made some risk-reduction behavior change. Developed from interviews conducted by outreach workers with target population members, the stories explain how and why the role model took steps to practice HIV risk-reduction behaviors and the positive effect it has had on their lives. The stories depict movement from one specific stage of change to the next, and this initial stage matches the predominant stage of change in the target population. Role model stories contain the behavior change message to deliver to the target population through outreach by peer advocates or messengers.

After staff is trained on interviewing (CID) for RMS, potential role models are recruited and screened. Appropriate role models who have demonstrated a reduced risk behavior are interviewed and the story is written and edited from the interview transcript. A format and layout for the story is developed and the product is reviewed and edited by staff. Sample stories are included in the intervention kit and can be used as models. Once approved, the publication is printed and combined with prevention materials, if used.

Peer Advocates

Peer advocates are recruited and trained to disseminate role model stories. The trained peer advocates use conversation to reinforce the messages in the role model stories. In their interactions with the community, the peer advocates encourage other target population members to read and talk about the stories within their own social network. By doing this, peer advocates assist their peers in more immediately relating to the content of the role model stories and help encourage peers to engage in risk-reduction or health-enhancing behaviors. For example, if the role model story demonstrates how the main character got tested for HIV, then the peer advocate encourages the target population member to think about that behavior change. Peer advocates also distribute prevention materials such as condoms and bleach.

Once peer advocates are recruited, screened and trained, they work with staff outreach workers and other staff to identify areas for distribution of RMS and prevention materials. Peer advocates distribute materials to and interact with the target population at times and frequencies agreed upon with the outreach worker. Regular meetings, trainings and appreciation events for peers are held at the agency and incentives are provided to them.

RESOURCE REQUIREMENTS

The minimum human resources required for Community PROMISE are a program manager at 25-100% time, one to several outreach workers at 100% time, role model story writing and production staff at 40-50% time and a support staff member at 50% time. The staff number and time can be increased depending on the size of the program. Peer advocates are not paid and work on a volunteer basis. However incentives are provided to them regularly, and they should have input on what type of incentives best suit them.

Other material resources include:

- Computer, printer, and software for word processing, desktop publishing, and data management and analysis
- Telephones, fax machine, copier, and equipment maintenance
- Digital camera (if you will be doing your own pictures for the publications) or photographer and scanner for role-model publications
- Production and printing
- Transportation for outreach workers
- Incentives for peer advocates (hats, hygiene kits, etc)
- Prevention materials to package with printed materials

RECRUITMENT

Recruitment of participants for Community PROMISE occurs at several levels. First, there is recruitment of individuals to participate in the community identification process. These individuals are invited to share their knowledge of the target population in focus groups, interviews or surveys.

Second, target population members are recruited by outreach workers to be interviewed, in order to create role model stories. These individuals can be identified during the community identification process or through referrals by outreach workers, STD/HIV test sites and other people who interact with members of the target population.

A third level of recruitment is of peers from the target population to distribute role model stories and prevention materials and reinforce prevention messages. Peers can be identified and recruited during the community identification process or through interaction with target population and community members. They can also be recruited through street outreach, at key sites such as local hang-outs, and through referral from community members.

Fourth, target population members are recruited by peer advocates to be recipients of role model stories and prevention materials. Depending on the message in the role model story, peer advocates recruit peers into counseling, testing and referral services, and other prevention and treatment services. The community identification process and the peer's familiarity with the target population environment will identify the proper venues and methods for role model story and materials distribution and interaction between the peer and target population.

PHYSICAL SETTING CHARACTERISTICS

Community PROMISE takes place in several settings, depending on the intervention activity. The community identification process occurs in community locations such as stores, bars, on the street, or even in agency offices. The interviewing of target population members by outreach workers or staff for role model stories occurs in a private setting such as agency offices or in community locations. The distribution of role model stories and materials occurs in locations

identified as appropriate in the community identification process. These are primarily venues where peer advocates find and work with the target population.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement Community PROMISE, the following policies and procedures should be in place to protect participants and the agency:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data, behavioral and clinical surveillance, and the state or local HIV prevention plan created with input from the state or local community planning group(s).

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Linkage of Services: Recruitment and health education and risk reduction must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: Agencies conducting recruitment, outreach, and health education and risk reduction, must established a code of conduct. This code should include, but not be limited

to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Community PROMISE is a community-level intervention that relies on the outreach work of peer advocates and the role model stories of members of the target population. It is naturally adapted and tailored to each unique community environment to best fit the community's needs and culture. Agency resources will determine how the intervention is implemented and what modifications, if any need to be made to fit within budget limits. The intervention training and supporting materials provide suggestions for how agencies can adapt the intervention. However, the core elements are essential components of the program that can not be modified in any manner.

A strong component of quality assurance is preparing a plan to implement Community PROMISE. Developing a comprehensive implementation plan will facilitate understanding and "buy-in" from key stakeholders and increase the likelihood the intervention runs smoothly. Quality assurance on this intervention also requires that someone at the agency will provide hands-on leadership and guidance for the intervention—from preparation through institutionalization. Also, a decision maker is needed in the agency who will provide higher-level support, including securing resources and advocating for Community PROMISE, from preparation to institutionalization.

Fidelity to the core elements of Community PROMISE is essential to assure the quality and effectiveness of the intervention. Throughout implementation, it is necessary to determine whether staff is delivering the intervention with fidelity to the core elements. The technical assistance manual contains a quality assurance tool to check fidelity to the core elements. In addition, training on the intervention and supporting materials such as the implementation manual and technical assistance manual provide implementing agencies with quality assurance tools to monitor implementation and measure fidelity. For example, the implementation manual contains a table detailing each task from the planning stage to the evaluation stage and listing the resources, skills and knowledge needed for tasks.

It is also necessary to identify and address any issues to assure the intervention is meeting the needs of agency clients and staff. Staff who are implementing Community PROMISE can develop their own Quality Assurance Checklist to help staff identify, discuss and solve problems in successfully implementing the intervention.

Evaluation is an important program management and quality assurance tool. Community PROMISE focuses on formative evaluation in the community identification process, process

monitoring and evaluation to assess the implementation process, and outcome monitoring to identify changes in the target population. The implementation manual in the intervention kit provides guidance and instruments such as interview guides, surveys, and tracking forms that can be adapted and used.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.A-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.
 - **I.B-** The proportion of person who access counseling and testing from each of the following interventions: individual level interventions and group level interventions.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
 - **V.A -** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

¹The CDC AIDS Community Demonstration Projects Research Group (1999). Community-Level HIV Intervention in 5 Cities: Final Outcome Data from the CDC AIDS Community Demonstration Projects. American Journal of Public Health. 89:336-345.

²Corby NH, Wolitski RJ. (Eds.). (1997). Community HIV prevention: The Long Beach AIDS Community Demonstration Project. Long Beach, CA: The University Press, California State University, Long Beach.

For more information on the Community PROMISE intervention, training and technical assistance, or to get your name on a list for a future training, please go to the website: www.effectiveinterventions.org.

SECTION 2: Targeted Outreach and Counseling, Testing, and Referral for High Risk Individuals

Activities included in this section are intended to help agencies target HIV counseling and testing to persons at high risk for HIV. Both traditional and rapid HIV testing procedures are included. These activities include HIV counseling and testing in traditional settings such as counseling, testing, and referral (CTR) sites and medical settings, as well as non-clinical settings such as correctional facilities, social functions, and other venues where persons at high risk congregate.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF COUNSELING, TESTING AND REFERRAL

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF HIV COUNSELING, TESTING AND REFERRAL

CDC estimates that 850,000 to 950,000 persons in the United States are living with HIV; of those, an estimated 25% are unaware of their infection. Evidence suggests that as many as two-thirds of the estimated 40,000 new HIV infections each year occur through transmission from persons who are unaware of their HIV status. Research also demonstrates, however, that after a positive HIV test result individuals generally decrease their risk behavior.¹

HIV Counseling, Testing, and Referral (CTR)^{2,3} refers to a collection of activities designed to increase a client's knowledge of his/her HIV serostatus, encourage and support risk reduction, and to secure needed referrals for appropriate medical, prevention, and partner counseling and referral services (PCRS). CTR can be provided in a number of settings using a variety of methods, but all CTR services address 5 basic requirements:

- 1) Inform clients about HIV transmission routes, the HIV antibody testing process, and the meaning of a positive or a negative test result.
- 2) Provide client-centered counseling around issues of recognizing one's risk for HIV infection, risk-reduction, and the need for testing.
- 3) If appropriate, test clients using the best available method.
- 4) When using the rapid HIV test, all standards and procedures related to the use of the rapid test including guidelines for providing preliminary results and obtaining specimens for confirmatory testing are followed (see Procedural Guidance for Rapid Testing in Non-Clinical Settings in this document for additional information on the rapid HIV test).
- 5) Address needs for additional services and provide suitable referrals to meet those needs.

CTR can be delivered anonymously or confidentially, but it should be voluntary and undertaken only with informed consent. Several HIV test technologies have been approved by the Food and Drug Administration including tests of different fluids (whole blood, serum, plasma, oral fluids, and urine) and durations (e.g., rapid tests) offering flexibility in testing option to facilitate client access to and acceptability of testing.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. CTR has 8 core elements which include:

- 1) HIV CTR is a voluntary service that can only be delivered after informed consent is obtained.
- 2) Information and education are provided regarding:
 - a. risk for transmission and how HIV can be prevented
 - b. the type of HIV antibody test used
 - c. the meaning of the test result including a discussion of the window period for HIV seroconversion (the time after infection, before antibodies are produced by the body in which and antibody test might be negative despite the presence of HIV)
 - d. where to obtain further information, counseling, or other services (medical or mental health care)
- 3) Client-centered counseling is provided to address the client's readiness for testing as well as his/her personalized risk assessment, steps taken to reduce risk, risk-reduction goals, support systems, referral needs, and plans for obtaining results if necessary (if testing is provided and the agency is not using rapid testing).
- 4) In conjunction with the state and/or local health departments and community mental health providers, establish guidelines and define sobriety standards for counselors to use to determine when clients are not competent to provide consent. These guidelines should be unambiguous and easy to implement.
- 5) HIV testing is conducted using a Food and Drug Administration (FDA) approved testing technology. When rapid HIV testing is offered, please see the Procedural Guidance for Implementation of Rapid Testing in Non-Clinical Settings in this document.
- 6) Test results are delivered in a supportive fashion and in a way that is understandable to the client.
- 7) Referral needs in support of risk reduction or medical care are assessed and appropriate referrals are provided with assistance linking clients with providers. A system must be in place for emergency medical or mental health referral if needed.
- 8) Referrals made and completed are tracked.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These

characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. CTR has 5 key characteristics:

- Information giving and educational elements of testing may be provided through face-to-face contact, in small or large group settings, or using brochures, handouts, videos, tape recordings, or other non-personalized information delivery manner
- Client-centered counseling and test results should be delivered in an individual, face-to-face session. While some providers have given negative test results over the telephone when a face-to-face session is not feasible, it is recommended that positive results be given in person to ensure the client has the necessary support and completes referrals for care and prevention services.
- A variety of specimens and test types are used in conducting HIV-antibody testing depending on the setting in which it is conducted and the needs of the organization and the client
- Service referrals that match the client's self-identified priority needs are more likely to be completed, however priority should be placed on referrals for medical care and PCRS (for clients testing positive), and for prevention and support services.

Procedures describe the activities that make up the content of the service and provide direction to agencies or organizations regarding delivery of the service. Procedures for CTR follow:

HIV CTR may be anonymous (the client's name is neither known nor solicited, and is not recorded) or confidential (the client provides his/her name and may or may not provide additional contact information), and it may be provided by self-referral (the client has made the decision to seek services individually) or by referral from other related services (medical or mental health care, substance abuse treatment, homeless shelters, partner counseling and referral services). In addition, it may be accessed in a clinic or office setting, or it may be brought to less traditional venues and provided as a part of outreach, or other services (PCM, other prevention interventions). In each of the instances of testing, however, a similar set of procedures is followed. If agency is using rapid HIV testing technologies, please review the *Procedural Guidance for Implementation of Rapid Testing in Non-Clinical Settings* in this document.

Information-Giving and Education: The client is first given information about HIV and the antibody test. This information must include a discussion of the risk factors for HIV and the how HIV can be prevented, the type of test to be used, and the manner in which a specimen will be collected for testing. The timeframe for testing should be also discussed including when the results will be available (and the importance of obtaining test result), and what positive and negative test results may indicate. The client should be counseled regarding the window period for HIV seroconversion so that he/she can determine if testing is appropriate or if testing at a later time might provide more information. Finally, referral to partner counseling and referral services (PCRS) in the case of a positive result should be discussed. When all aspects of the test have been disclosed, the client is able to make an informed decision regarding whether he/she should be tested. The client should then provide consent (verbal or written, as required by state/local policy) indicating his/her willingness to be tested for the presence of the HIV antibody. If testing is anonymous, the client should be informed that providing a sample for testing implies consent.

Client-Centered Counseling: Client-centered counseling techniques are used to help the client to determine his/her readiness for testing including support systems to access while waiting for and after receiving the test results. The client's ability to cope with a positive test result should also be assessed.

If the client indicates a willingness to continue with the test, an individualized risk assessment is conducted to determine the client's risk behaviors and the relative level of risk that they entail. This information should be shared with the client to assist him/her in developing an enhanced self-perception of risk and to enable the client and the counselor to identify, acknowledge, and understand the details and context of the client's risk. Factors associated with continued risk behavior that might be important to explore include using drugs or alcohol before sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, receiving reinforcement for frequent unsafe practices (e.g., a negative HIV test result after risk behaviors), and perceiving that vulnerability is associated with "luck" or "fate". Keeping the focus of the assessment personal is intended to help the client identify concrete, acceptable protective measures to reduce personal HIV risk.

The counselor should acknowledge, and provide support for positive steps that the client has already made toward risk-reduction and then negotiate a concrete achievable behavior-change step that will reduce HIV risk. Counselors should focus on reducing the client's current risk and limit general education regarding HIV transmission modes and the meaning of HIV test results. Although the optimal goal is to eliminate HIV risk behaviors, small behavior changes can reduce the probability of acquiring or transmitting HIV. Behavioral risk-reduction steps should be acceptable to the client and appropriate to the client's situation. For clients with several high-risk behaviors, the counselor should help clients focus on reducing the most critical risk they are willing to commit to changing. The step should be relevant to reducing the client's own HIV risk and should be a small, explicit, and achievable goal, not a global goal. Identifying the barriers and supports to achieving a step, through interactive discussion, role-play modeling, recognizing social support or other methods will enhance the likelihood of success. In addition, the counselor should provide skill-building opportunities related to the goal including having the client demonstrate proper condom usage or paraphernalia cleaning (with feedback) or role-playing negotiation of abstinence or safer sex in a relationship. For clients with ongoing risk behaviors, referral to additional prevention and related support services is encouraged. A structured protocol outlining session goals can help keep the counselor focused on risk reduction and ensure consistent delivery from client to client. An example of a counseling protocol from the RESPECT model of HIV prevention counseling can be found at

<http://www.cdc.gov/hiv/projects/respect/default.htm>

Conducting the Test: After counseling, referrals are provided (see below regarding making referrals) if necessary and the HIV-antibody test is conducted according to the procedures outlined by the test's manufacturer, and a follow-up appointment is scheduled if necessary or desirable. If the rapid HIV-antibody test is used a follow-up appointment may not be necessary, but for traditional HIV-antibody testing results are given at a second appointment. The counselor should schedule the appointment at the time and place that is most likely to result in the client

returning for results.

Providing Results: Results should be provided at the beginning of the results-giving session using explicit language. Counselors should never ask the client to guess the test results. Counselors should, however, clarify test results (for an explanation of test results, please refer to the *Revised Guidelines for HIV Counseling, Testing, and Referral*.¹) and discuss implications for continued risk reduction commitment. This discussion should address personal HIV risk reduction for clients with negative test results (including reviewing progress on goals set at the previous counseling session) and additional considerations for clients with positive or indeterminate test results.

For clients with a positive test result, the counselor may need to provide psychological support and/or make a referral for additional counseling if indicated. The counselor should ensure that the client knows where and how to obtain further information and services, and referrals should be provided for medical evaluation, care, and treatment (including sexually transmitted disease (STD) screening and care and screening and vaccination or treatment for viral hepatitis, and referral for reproductive health services). The counselor should ensure that the client has accurate information about how HIV is transmitted and how transmission can be prevented. Misconceptions regarding HIV transmission risk should be elicited and addressed, and the counselor should provide prevention counseling to address strategies for prevention of other STDs or bloodborne infections.

The counselor should assess the need for, and provide or make referrals for other prevention services (individual- or group-level interventions or PCM). The client should also be counseled regarding whom to notify of his/her positive test result, and a discussion of and referral to PCRS should be provided.

Referral: Referrals for additional services may be made at any point in the CTR process. Some referrals that should be considered include:

- STD screening and care
- Viral hepatitis screening, vaccination, and treatment
- Housing
- Food
- Transportation
- Domestic violence
- Reproductive health services
- Chemical dependency prevention and treatment
- Mental health services
- Legal services
- Other support services

CTR sites should develop and maintain a referral resource guide, and nurture strong working relationships with provider agencies. Key contacts from these agencies should be identified, and formal written agreements should delineate the roles and responsibilities of each agency. Sites should review their referral agreements periodically and modify them as appropriate. If barriers

to successful referrals exist these should be addressed initially and on an ongoing basis.

When making a specific referral for a client, the counselor must consider the most appropriate service provider for the client, considering such issues as the client's culture, language, sex, sexual orientation, age, or developmental level. The counselor should work with the client to identify barriers to completing the referral and the means of addressing those barriers. Referrals are most likely to be completed if they match the client's self-identified priority needs, the client is provided with a contact at the agency to which he/she is referred, and the counselor is able to provide some personalized information about the agency including a contact name, eligibility requirements, location, hours of operation, and the telephone number. More than one referral option should be provided if possible. The referral may be also facilitated if the counselor can call the service provider with the client, however, prior to exchanging any information regarding a client, the counselor must have a signed informed consent form to share private information from the client.

All referrals should be documented, and tracked to determine if they were completed. If the client did not, barriers to completion should be addressed. If the referral was completed, satisfaction with the referral should be assessed and this information should be maintained in the referral resource guide. If services were unsatisfactory, additional referrals should be made if possible. Information obtained through follow-up of referrals can identify barriers to completing the referral, responsiveness of referral services in addressing client needs, and gaps in the referral system.

RESOURCE REQUIREMENTS

Paid or volunteer staff members implementing CTR must be trained in HIV counseling, testing, and referral. If rapid HIV testing will be used, the staff member must be trained in the delivery of rapid HIV testing and all policies, quality assurance requirements, and local and state requirements related to rapid HIV testing must be followed (see *Procedural Guidance for Implementing Rapid Testing in Non-clinical Settings* in this document). Staffing levels will vary depending on the number of tests that are required. Depending on the needs of the clients, the abilities of the counselor, and the type of test (rapid or traditional), individual counselors may provide between one and two tests per hour. Providing positive results will take additional time. Agencies should staff their programs according to the projected need for testing in their area. This information can be obtained from an appropriate needs assessment and a review of the local epidemiological profile (the HIV prevention community plan and other sources of relevant information).

RECRUITMENT

The following recruitment strategies can be used to reach clients for CTR:

- Recruit from HIV prevention counseling, prevention case management, or other agency services

- Recruit from other community based organizations that serve high-risk populations, e.g., substance abuse treatment facilities, correctional facilities, shelters.
- Send press releases and/or public service announcements to radio stations and TV stations that are targeted to specific populations at high risk for HIV
- Advertise in local newspapers (including neighborhood/gay/alternative papers, etc.)
- Post announcements on the Internet

Agencies choosing to implement Counseling, Testing and Referral services, should review the Procedural Guidance for Recruitment in order to choose a recruitment strategy that will work in the setting in which they plan to implement CTR services.

PHYSICAL SETTING CHARACTERISTICS

CTR can be implemented at any location where confidentiality of clients can be ensured (e.g., private area or room). The agency must be able to safely collect specimen samples of clients who wish to be tested according to minimal standards as outlined by the Occupational Safety and Health Administration (OSHA).

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement CTR services the following policies and procedures should be in place to protect clients, CTR providers, and the agency:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in appropriate language the agency's responsibility and the client's rights. In some states informed consent is not required to be written and can be given verbally. **Client participation must always be voluntary and documentation of this informed consent must be maintained in the agency records.**

Legal/Ethical Policies: It is important to keep in mind that the implementation of CTR services deal with the provision of services that requires specialized training and deals with private client medical information. Agencies must know their state laws regarding who may implement CTR procedures and about disclosure of a client's HIV status (whether positive or negative) to sexual partners and other third parties. Agencies are obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Safety: CTR services that are provided in non-traditional settings may pose potentially unsafe situations, e.g. the risk of transmitting blood borne pathogens. Agencies should develop and maintain written detailed guidelines for personal safety and security in non-traditional settings, for assuring minimal safety standards (including biohazard waste disposal) as outlined by the

Occupational Safety and Health Administration (OSHA) and to safeguard the security of the data collected, client confidentiality and the chain of custody for testing supplies and collected client specimens. Agencies must ensure that CTR providers are aware of and comply with safety guidelines.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality. Agencies should have written protocols on how to collect, document, analyze, and use CTR data according to State and local policies.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to clients as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for counselors and clients and review of the setting should be in place when implementing CTR:

Counselor: Agencies should have a training program in place for all new employees, existing employees and volunteers that will be providing CTR services. This program should ensure that all CTR providers receive adequate training, annual training updates, continuing education and adequate supervision to implement CTR services and the rapid HIV test if appropriate. It should also ensure that CTR providers are skilled and competent in the provision of services by using observed practice of CTR sessions with feedback to counselors and of rapid HIV test procedures if needed. Agencies should have in place a mechanism to assure that all testing protocols are

followed as written. QA activities can include observation as well as role-play demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should assist counselors with intervention delivery and skill development. Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required. For CBOs using rapid HIV test technology, please review the *Procedural Guidance for Rapid Testing in Non-Clinical Settings* in this document.

Client: Clients' satisfaction with the services and their comfort should be assessed periodically.

Setting: Supervisors should periodically review the setting to ensure that it is private and confidential and that the waiting time for a test does not create a barrier to testing.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report client level data;
- Collect and report standardized process and outcome data consistent with CDC's requirements;
- Use the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may, under certain circumstances, use a local system provided that it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **II.A-** Percent of newly identified, confirmed HIV positive test results among all tests funded by CDC and reported by your organization.
 - **II.B-** Percent of newly identified, confirmed HIV positive test results returned to clients.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.

KEY ARTICLES AND RESOURCES

¹CDC. Advancing HIV prevention: New strategies for a changing epidemic. MMWR 2003; 52;3 329-332.

²CDC. Revised guidelines for HIV counseling, testing, and referral. MMWR 2001; 50 RR-19.

³Powderly WG, Mayer KH. (2003). Centers for Disease Control and Prevention revised guidelines for human immunodeficiency virus (HIV) counseling, testing, and referral: Targeting HIV specialists. Clin Infect Dis [year?]; 37:(15), 83

CDC, Division of HIV/AIDS Prevention-Intervention, Research and Support, Capacity Building Branch, Training and Development Team; HIV Prevention Train the Trainer Course Series: Fundamentals of HIV Prevention Counseling, “Making Effective Referrals” Unit 5
Assuring the Quality of HIV Prevention Counseling: Practical Approaches for Supervisors

CDC. Revised Guidelines for HIV Counseling, Testing, and Referral.
<http://www.cdc.gov/mmwr/PDF/rr/rr5019.pdf>

RESPECT Counseling, Testing, and Referral Protocol.
<http://www.cdc.gov/hiv/projects/respect/default.htm>

Rapid Testing website. http://www.cdc.gov/hiv/rapid_testing/

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). National Standards for Culturally and Linguistically Appropriate Services in Health Care.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators.

U.S. Department of Labor, Occupational Safety and Health Administration. Occupational Safety and Health Standards. Toxic and Hazardous Substances. Blood borne Pathogens. Part 1910.1030, Appendix A

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF RAPID TESTING IN NON-CLINICAL SETTINGS

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF RAPID TESTING IN NON-CLINICAL SETTINGS

Outreach efforts for HIV prevention activities provide access to hard-to-reach populations at high risk for HIV. Bringing HIV prevention counseling, testing, and referral (CTR) to these outreach sites through the use of mobile vans and HIV tests designed for oral fluid has helped to increase knowledge of serostatus among many groups.

Testing programs in non-clinical venues are more likely to reach members of some racial and ethnic minorities and persons at increased risk for HIV. Compared with persons tested at conventional testing sites, those tested at non-clinical sites were twice as likely to report high-risk heterosexual contacts and 3 to 4 times as likely to report injection drug use or male-to-male sex.¹ A California outreach program called Neighborhood Interventions Geared to High-risk Testing (NIGHT) offers street outreach, HIV counseling and testing, and referrals through the use of mobile vans. NIGHT was the source of more than 104,000 tests during 1997 and 2001. Compared with other testing sources, NIGHT reached a higher proportion of African Americans (28% versus 13%), injection drug users (23% versus 11%), stimulant drug users (45% versus 25%), and commercial sex workers (12% versus 5%).²

The rate of HIV-positive tests in non-clinical settings is generally high and consistently higher than at conventional testing sites.¹ In Wisconsin, persons tested in outreach were 23% more likely to test HIV-positive than those tested in clinics.³ Of the 597 persons tested in mobile vans and street outreach in a 1999 initiative to enhance prevention efforts in African American and Latino communities in 4 U.S. cities, 8.7% were HIV-positive.⁴ In South Carolina, 54% of men approached in a gay bar agreed to oral fluid testing; although 78% had been tested before, 6% were newly diagnosed with HIV.⁵ In CDC's Young Men's Survey in 7 cities, a total of 3,592 15-to-22-year-old men who have sex with men approached in 194 non-clinical testing settings (public venues) consented to HIV testing. Overall prevalence was 7.2%. Although 79% of the men had been tested previously, 203 (82%) of the 249 HIV-positive men did not know that they were currently HIV-positive.⁶

Unfortunately, many persons tested in non-clinical settings do not return for their test results. CDC's national data from 2000 indicate that results from nearly half of the HIV-positive tests performed in non-clinical settings were never received. In California's NIGHT program, mobile testing clients were three times less likely to receive their test results than clients tested at conventional sites. In contrast, limited experience to date with rapid testing in outreach programs is encouraging. In a Minnesota program, an outreach worker regularly visited community-based

organizations (CBOs), homeless shelters, chemical dependency programs, and needle exchange programs to offer rapid HIV testing. When results were provided the same day, 99.9% of those tested received their HIV test results.⁷

Interviews of persons at non-clinical settings reveal features important to the success of this type of testing. For high-risk persons at a needle exchange program and gay bath houses, 36% of those who had never been tested and 28% of those who had delayed testing gave “not wanting to go to a clinic” as their reason.⁸ Participants in other testing initiatives cite a desire to receive HIV results immediately and a need for testing during expanded hours as important reasons to increase alternative testing opportunities.⁹

The OraQuick Rapid HIV-1 Antibody Test, which can be suitable for use in selected non-clinical settings and can provide results in 20 minutes, offers an opportunity to take advantage of the benefits of outreach testing and ensure that tested persons receive their results. It is important to realize that positive tests from any setting must always be confirmed using a second, more specific test (e.g., the Western Blot). Therefore, until the positive result is confirmed, the result is determined to be “preliminary positive.”

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention’s intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Rapid testing in non-clinical settings has 7 core elements which include:

- 1) Assess the community to determine
 - a. in which populations HIV is likely to be under-diagnosed (because risk is underestimated, and/or because traditional counseling, testing, and referral services are not used)
 - b. where persons at risk and/or underdiagnosed can be reached.
- 2) The agency must have a written agreement with the state Health Department and/or a laboratory to ensure compliance with the Clinical Laboratory Improvement Amendments (CLIA) and state and local regulations and policies.
- 3) A clear supervisory structure should be delineated to ensure responsibility for training and guidance, oversight for testing procedures, and coordination.
- 4) Train or ensure training of non-clinical providers to perform rapid HIV testing including the following essential elements:
 - a. Perform the test, including procedures performed before, during, and after testing
 - b. Integrate rapid testing into the overall counseling and testing program
 - c. Develop and implement a quality assurance (QA) program
 - d. Collect and transport specimens for confirmatory testing

- e. Ensure specimen integrity
 - f. Document and deliver confirmatory testing results to persons whose rapid test results had been preliminary positive
 - g. Comply with universal and biohazard safety precautions
 - h. Ensure confidentiality and data security
 - i. Ensure compliance with relevant state or local regulations
- 5) In conjunction with the state or local health department and community mental health providers, establish guidelines and define sobriety standards for counselors to use to determine when clients are not competent to provide consent. These guidelines should be unambiguous and easy to implement.
 - 6) Confirmatory testing of preliminary positive tests must be assured.
 - 7) Clients with a confirmed HIV-positive diagnosis must be provided with or referred for medical evaluation, partner counseling and referral services, and other appropriate prevention services.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Rapid Testing in non-clinical settings has 3 key characteristics:

- Arrange appropriate referral agreements (for medical and social services) and develop strategies for follow-up.
- Obtain detailed locating information on clients whose test results are preliminary positive so that they can be contacted and encouraged to come in for care if they fail to return for their follow-up appointment. The Health Department and the testing program should specify who is responsible for follow-up if clients fail to return for confirmatory test results.
- Assemble the testing supplies for easy storage and transportation to each testing site. Individually packaged rapid test kits include all the supplies and materials necessary to facilitate single client testing in non-clinical settings.

Procedures describe the activities that make up the content of the service and provide direction to agencies or organizations regarding delivery of the service. Procedures for providing rapid HIV-testing in non-clinical settings follow:

By allowing agencies to bring testing into the community and provide test results quickly, the OraQuick Rapid HIV-1 Antibody Test can be used to reach groups in which HIV-infection has been traditionally under-diagnosed because people do not recognize that they are at risk for HIV infection, and/or they do not use traditional HIV counseling, testing, and referral services. Agencies considering the use of rapid testing in non-clinical, or outreach, settings should begin by assessing their community. Agencies should seek input from their community planning groups, other community based service providers, and representatives of their target populations

to determine the venues where persons at high risk for HIV are likely to spend time, and where rapid testing services could be delivered without an appointment, with little waiting time, and with no barriers such as transportation (see the Physical Setting Characteristics section below).

If the needs assessment indicates that rapid testing outside of a clinical setting is both appropriate and feasible, the agency must ensure an understanding of, and compliance with the Clinical Laboratory Improvement Amendments (CLIA) and all state and local regulations and policies through a written agreement with the state or local health department and/or laboratory which delineates responsibility for training and guidance, oversight for testing procedures, and coordination of services and which ensures that confirmatory testing of preliminary positive results is provided.

CDC recommends that any individual who is responsible for the delivery of the rapid test should be trained in and familiar with the fundamentals of client-centered HIV prevention counseling; performing the rapid test; providing and interpreting test results, including the meaning of negative, preliminary positive, and invalid test results; providing referrals for services (including for social services as well as medical care), and reporting of positive test results to the state or local health department.

Delivery of the rapid test in non-clinical settings differs from standard CTR, however, in that testing materials must be carried to the testing site. Individually packaged rapid test kits include all the supplies and materials necessary to facilitate single client testing in non-clinical settings; agencies must devise a means for easy storage and transport of testing materials. In addition, because the test is not conducted in a clinic setting, specimens collected for confirmatory testing must be transported to a laboratory for analysis. Specimen handling and tracking procedures must be devised to assure the safety and integrity of the specimen, and to comply with Occupational Safety and Health Administration (OSHA) regulations for handling of infectious waste. An exposure control plan must be devised for potential occupational exposures.

Because preliminary positive results must be confirmed with laboratory testing, detailed locating information must be obtained for all persons with a preliminary positive test so that they may be contacted to come in for care should they fail to return for their follow-up appointment. The state or local health department and CBO must specify who is responsible to follow-up in the event that a client fails to return for confirmatory test results. In some states, preliminary positive results cannot be given to clients. In these cases, consideration should be given, where appropriate, to eliminating such barriers to rapid testing.

Training is available from CDC which addresses the essential elements of HIV rapid test delivery. Agencies should also frequently review the package insert for the rapid HIV test to note any recommended changes related to test delivery and use. Agencies who choose to implement rapid testing in non-clinical settings should determine the most appropriate way to integrate this service into their existing CTR services.

RESOURCE REQUIREMENTS

Staff members implementing rapid testing in non-clinical settings must be trained in HIV counseling, testing, and referral and in the delivery of rapid HIV testing. Training should include all topics noted in the Quality Assurance section below. Staffing levels will vary depending on the number of tests that are required. Depending on the needs of the clients and the abilities of the counselor, individual counselors may provide between one and three tests per hour. Providing positive results will take additional time. Agencies should staff their programs according to the projected need for rapid testing in an area. This information can be obtained from an appropriate needs assessment and a review of the local epidemiological profile (the HIV prevention community plan and other sources of relevant information).

RECRUITMENT

Agencies choosing to implement rapid testing in non-clinical settings, should review the Procedural Guidance for Recruitment in order to choose a recruitment strategy that will work in the setting in which they plan to implement these services.

PHYSICAL SETTING CHARACTERISTICS

Rapid testing can be implemented at any location where confidentiality of clients can be assured (e.g., private area or room) and where a specimen sample can be collected according to minimal standards as outlined by OSHA. In addition, the setting must have a flat surface, acceptable lighting, and temperature control (59-80°F), and the priority population must remain at the venue long enough to receive counseling, testing, and results.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement rapid testing in non-clinical settings the following policies and procedures should be in place to protect clients, the agency, and the test provider:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in appropriate language the agency's responsibility and the client's rights. In some states informed consent is not required to be written and can be given verbally. Client participation must always be voluntary and documentation of this informed consent must be maintained in the agency records. Clients offered HIV testing at non-clinical venues may be under the influence of alcohol or drugs or have chronic mental health conditions, any of which may interfere with their ability to provide informed consent for voluntary HIV testing, or to understand test results. Agencies should work with their state or local health department and with community mental health providers to establish guidelines and define sobriety standards for counselors to use to determine when clients are not competent to provide consent. These guidelines should be unambiguous and easy to implement. Because regulations vary by state, agencies should be familiar with informed consent requirements in their state.

Legal/Ethical Policies: It is important to keep in mind that the implementation of rapid testing in non-clinical settings requires specialized training and deals with private client medical

information. Agencies must know their state laws regarding who may implement CTR and rapid testing procedures and about disclosure of a client's HIV status (whether positive or negative) to sexual partners and other third parties. Additionally, some state laws prohibit the disclosure of preliminary positive test results. Agencies must also know, and adhere to all CLIA regulations for testing, documentation, and use of logs relating to test implementation. Finally, agencies are obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Safety: CTR and rapid testing services that are provided in non-traditional settings may pose potentially unsafe situations, e.g. the risk of transmitting blood borne pathogens. Agencies should develop and maintain written detailed guidelines for personal safety and security in non-traditional settings, for assuring minimal safety standards regarding specimen collection as outlined OSHA, and to safeguard the security of the data collected, client confidentiality and the chain of custody for testing supplies and collected client specimens. Agreements with law enforcement, owners of social venues such as bathhouses or sex clubs, neighborhood associations, and other key partners should be established before testing activities begin.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to clients as necessary. After preliminary positive rapid test results have been provided, follow-up procedures should be in place to ensure that the client returns for confirmatory test results. A follow up visit must be scheduled at the referral medical center where confirmatory test results and referrals for care can be provided. HIV counselors from the non-clinical site may accompany clients to the medical center to provide support and ensure continuity of care. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services,

Health Department/Community Based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

QUALITY ASSURANCE

Quality assurance activities for counselors and clients and review of the setting should be in place when implementing rapid testing in non-clinical settings:

Counselor: Agencies should have a training program in place for all new and existing employees providing rapid testing services. This program should ensure that all providers receive adequate training, annual training updates, continuing education, and appropriate supervision to implement rapid testing services including training on:

- Client-centered HIV prevention counseling
- Providing information to persons being tested before testing
- HIV transmission and prevention of HIV and other STDs
- The natural history of HIV
- Partner counseling and referral services
- Prevention case management
- Prevention and support services in the area
- Using gloves for personal protection
- Safe disposal of biohazardous waste, including used lancets
- Maintaining sufficient supplies and unexpired test and control kits (including proper storage and performance checks for new test kit lots and shipments with external controls)
- Maintaining and documenting the temperature of the room and refrigerator where the tests and controls are stored and testing is performed
- Performing quality control testing and taking action (e.g., contacting the supervisor or manufacturer) if controls do not work
- Collecting specimens
- Performing the steps in the test procedure
- Reporting results
- Referring specimens or persons being tested for confirmatory testing and manage confirmatory test results
- Recording test and quality control results
- Conducting external quality assessment (please refer to the rapid HIV test website in the resources section)
- Reviewing records and storing and destroying them when they are outdated (how long test result records are kept as part of a medical record may be subject to State or other requirements)
- Troubleshooting and taking corrective action when things go wrong

The training should ensure that providers are skilled and competent in the provision of services by using observed practice of counseling skills integrating the rapid HIV test and of all steps of the rapid test. QA activities can include direct observation of sessions as well as role-play

demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should assist counselors with intervention delivery and skill development. Control kits, available from OraSure Technologies, should be used to ensure reliability and validity of the test process and materials. CDC also offers the *Model Performance Evaluation Program* to ensure accurate testing.

Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required.

Client: Clients' satisfaction with the services and their comfort should be assessed periodically. Process monitoring systems should also track the number referrals made and completed as well as response to the service.

Setting: Supervisors should periodically review the settings to ensure that they are private and confidential, that the requirements of the test are met, and that the waiting time for a test does not create a barrier to testing.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report client level data;
- Collect and report standardized process and outcome data consistent with CDC's requirements;
- Use the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may, under certain circumstances, use a local system provided that it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.A-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.
 - **II.A-** Percent of newly identified, confirmed HIV positive test results among all tests funded by CDC and reported by your organization.
 - **II.B-** Percent of newly identified, confirmed HIV positive test results returned to clients.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
 - **V.A-** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

¹Greby S, Frey B, Royalty J, et al. Use of simple oral fluid HIV-tests in CDC-funded facilities. In: Program and abstracts of the XIV International Conference on AIDS; July 2002; Barcelona, Spain. Abstract TuPeD4991.

²Rasmussen H, Chen M, Myrick R, Truax S. An evaluation of California's neighborhood interventions geared to high-risk testing (NIGHT) outreach program. In: Program and abstracts of the XIV International Conference on AIDS; July 2002; Barcelona, Spain. Abstract ThOrD1401.

³DiFrancesco W, Holtgrave DR, Hoxie N, et al. HIV seropositivity rates in outreach-based counseling and testing services: program evaluation. *J Acquir Immune Defic Syndr* 1998;19:282-288.

⁴Dean HD, Gates CH. Conducting HIV counseling, testing and referral within the context of rapid assessment, response and evaluation in crisis response team cities. In: Program and abstracts of the XIV International Conference on AIDS; July 2002; Barcelona, Spain. Abstract MoPeF3980.

⁵Sy FS, Rhodes SD, Choi ST, et al. The acceptability of oral fluid testing for HIV antibodies: a pilot study in gay bars in a predominantly rural state. *Sex Transm Dis* 1998; 25:211-215.

⁶Valleroy LA, MacKellar DA, Karon JM, et al. HIV prevalence and associated risks in young men who have sex with men. *JAMA* 2000; 284:198-204.

⁷Keenan PA, Keenan JM. Rapid HIV testing in urban outreach: a strategy for improving posttest counseling rates. *AIDS Educ Prev* 2001;13:541-550.

⁸Molitor F, Bell RA, Truax SR, et al. Predictors of failure to return for HIV test result and counseling by test site type. *AIDS Educ Prev* 1999;11:1-13.

⁹Spielberg F, Branson BM, Goldbaum GM, et al. Overcoming barriers to HIV testing: preferences for new strategies among clients of a needle exchange, a sexually transmitted disease clinic, and sex venues for men who have sex with men. *J Acquir Immune Defic Syndr* 2003; 32:318-328.

CDC Model Performance Evaluation Program for Rapid HIV Testing:
<http://www.phppo.cdc/mpep/enrollment.asp>

CDC Revised Guidelines for HIV Counseling, Testing, and Referral.
<http://www.cdc.gov/mmwr/PDF/rr/rr5019.pdf>

CDC Technical Assistance Guidelines for CDC's HIV Prevention Program Performance Indicators. <http://www.cdc.gov/hiv/dhap>

CLIA application and requirements: www.cms.hhs.gov/clia

NASTAD Primer on implementing rapid HIV testing:
<http://www.nastad.org/PDF/RAPIDPRIMER.PDF>

Occupational Safety and Health Administration: www.osha.gov

Product information, OraQuick Rapid HIV-1 Antibody Test: <http://www.orasure.com/products/>

Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test:
http://www.cdc.gov/hiv/rapid_testing/materials/QA_Guidelines_OraQuick.pdf

Rapid HIV Testing: www.cdc.gov/hiv/rapid_testing

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001).
National Standards for Culturally and Linguistically Appropriate Services in Health Care.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF ROUTINE TESTING OF INMATES IN CORRECTIONAL FACILITIES

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF ROUTINE TESTING OF INMATES IN CORRECTIONAL FACILITIES

In the United States, approximately 2 million people are currently incarcerated.¹ An additional 4 million individuals are on parole or probation.² Men represent the overwhelming majority of the incarcerated population (92%); however, the proportion of women has been steadily increasing in recent years.² Minority populations are disproportionately represented among people incarcerated, with recent estimates indicating that 12% of African-American males and 4% of Hispanic males in their twenties and early thirties are incarcerated.²

Prisons generally house individuals with sentences of 1 year or longer,³ and there are currently 1.3 million inmates housed in state and federal prisons.¹ Jails currently house roughly 600,000 inmates.² Jails are operated by a city or county and house people awaiting hearings, trials, transfer to prison, or misdemeanor convictions. People detained in jails usually serve less than 1 year. The majority serve less than two weeks.³ Most inmates are eventually released, but many are re-incarcerated within six months.⁴ This results in 7.5 million people released annually.⁵

Many individuals entering correctional facilities have a history of high-risk sexual behaviors, substance abuse, or both. As a result, high rates of HIV and sexually transmitted diseases (STDs) have been documented among persons entering the correctional system.⁵ In 1999, there were more than 25,000 (2.0%) federal and state prison inmates, and more than 8,600 jail inmates (1.7%) known to be HIV-positive.⁶ In addition, the prevalence of AIDS among prison populations is 5 times higher than that in the general U.S. population (0.60% versus 0.12%).⁶ Recent estimates suggest that nearly 25% of people living with HIV pass through the correctional system.⁷ Currently, less than half of the prison systems and few jails routinely provide HIV testing on entry.⁸ Therefore, many individuals who may be infected are not routinely offered HIV testing. Providing routine HIV prevention counseling and testing within the standard medical intake evaluation for all inmates can identify HIV infection among people who are either unaware of their status, or who have tested negative with a previous test and can confirm the status of inmates who report that they are HIV-positive. Routine HIV testing can either be in the form of standard enzyme immunoassay (EIA) and Western Blot testing or rapid HIV testing with appropriate confirmation testing. Health departments or agencies approved to provide partner counseling and referral services (PCRS) should initiate this service for contacts of these HIV infected persons.

Persons incarcerated for less than 30 days may not receive traditional HIV counseling, testing, and referral (CTR), and, if they do, they are likely to be released before their test results are available. Use of rapid HIV testing could help ensure this population receives their test results. The RESPECT 2 study showed that HIV CTR that used a rapid HIV-screening test was as effective as traditional HIV CTR.⁹

Routinely providing rapid HIV CTR services for persons incarcerated for less than 30 days can greatly increase the proportion of persons tested and notified of their test results prior to release so that PCRS, prevention, and care services can be secured both within the corrections system and after release. CBOs must collaborate with the state or local health department, state and local justice and correctional departments, and officials for the individual correctional facility to address the HIV prevention needs of their inmates. If rapid testing is implemented in the correctional setting, please see the *Procedural Guidance for Implementation of Rapid Testing in Non-Clinical Settings* in this document for further guidance.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Routine testing of inmates in correctional facilities involves 8 core elements which include:

- 1) All rules and regulations of the correctional facility must be adhered to closely to assure the safety of CBO employees, inmates, and facility staff.
- 2) HIV counseling and testing is routinely offered to all inmates with informed consent.
- 3) All CTR services are provided consistent with CDC's Revised Guidelines for HIV Counseling, Testing, and Referral.
- 4) When using the rapid HIV test, all standards and procedures related to the use of the rapid test including guidelines for providing preliminary results and obtaining specimens for confirmatory testing are followed (see *Procedural Guidance for Rapid Testing in Non-Clinical Settings* in this document for additional information on the rapid HIV test).
- 5) All tested inmates are notified confidentially, and in person of their HIV test result (whether HIV positive or HIV negative).
- 6) Persons infected with HIV are referred to partner counseling and referral services, medical care and treatment, and prevention services in the correctional facility, in the community, or both.

- 7) HIV-negative persons at high risk are referred to prevention services in the facility, in the community, or both.
- 8) For infected persons or HIV-negative persons at high risk being released from the correctional facility, referral and linkage to care, treatment, and prevention services in the community is essential.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Routine testing of inmates in correctional facilities has 6 key characteristics:

- Develop an information sheet with all relevant information regarding HIV prevention counseling, testing, and referral services to be distributed at inmate intake appointments.
- Establish a system to document consent for testing and test results, and to track specimens sent for confirmatory testing.
- Develop a system to document and track refusal of HIV testing.
- Testing of inmates may occur before, during, or shortly after the medical evaluation at intake into the correction facility.
- Collaborate with the correctional facility to devise a strategy for reporting positive results to the state Health Department.
- Key contacts should be identified within the CBO and at the correctional facility to provide accountability and continuity in the collaboration.

Procedures describe the activities that make up the content of the service and provide direction to agencies or organizations regarding delivery of the service. Procedures for routine testing of inmates in correctional facilities follow:

CBOs should initiate discussions with correctional systems that do not routinely offer HIV testing to inmates during the intake medical evaluation to determine their willingness to implement routine testing. Additionally, CBOs should assess the inclusion of rapid HIV testing in facilities implementing routine testing but not yet incorporating this new technology into their systems. CBOs must collaborate with the state or local health department, state and local justice and correctional departments, and officials for the individual correctional facility (including correctional officers and medical staff) to develop policies and procedures that promote successful training for CBO and correctional staff, and implementation of routine HIV screening and prevention services in correctional facilities and in the community. The CBO should work with facility officials to promote the importance of routine testing, and to address policies related to confidentiality and data security, documenting test results and refusals of testing, and providing inmates confidential notification of their HIV test results. The regulations of correctional facilities are designed for the protection of inmates, staff, and visitors to the facility; it is essential that agencies who wish to partner with a jail or prison understand and follow all rules of the facility.

If the facility does not already have an information sheet that has been approved by the Health Department or Department of Corrections, the CBO should collaborate with medical personnel at the jail or prison to design one that can be given to all inmates prior to their intake medical appointment. The sheet should describe the risk factors for transmitting or acquiring HIV, features of the HIV antibody test and possible results, and HIV prevention, support, and care services available within and outside of the facility. It should also advise the inmate that HIV prevention counseling, testing, and referral is provided as a routine part of the intake medical evaluation. Informed consent for the HIV test should be obtained in a manner consistent with state and facility policy. The information sheet can be used as a stimulus for the care provider to discuss HIV risk with the inmate, and to refer him or her to the CBO representative on site for CTR services.

Depending on the inmate's projected length of incarceration, a CBO representative may choose to use either standard HIV testing with an EIA test followed by a Western Blot if indicated, or rapid HIV testing with Western Blot confirmatory testing for preliminary positive diagnoses. Regardless of which strategy is used, testing must follow CDC's Revised Guidelines for HIV Counseling, Testing, and Referral and anyone providing this service should be certified in HIV prevention counseling, testing, and referral. In addition, if the rapid test is used, the CBO representative should have completed training in proper use of the test.

The CBO should work with correctional officials to identify HIV-related services within the facility and in the community. The CBO and correctional officials should work together to refer all persons with a positive test and HIV-negative persons at high risk for infection to appropriate care, treatment, and/or prevention services. The services to which the inmate is referred will be determined by his or her needs and the length of the inmate's incarceration. When possible, the initial care appointment should occur while the inmate is in the correctional facility. Inmates who test positive should be offered and encouraged to participate in partner counseling and referral services (PCRS) either by referral to the local or state health department, or by the CBO if appropriate. Other services, including discharge planning should be available either from the correctional facility, the CBO, or by referral. Relationships between the CBO, the correctional facility, state and/or local health departments and other service providers within, and outside of the facility should be formally documented and the CBO and correctional facility should designate key contacts to provide accountability and continuity in the collaboration and referral process.

RESOURCE REQUIREMENTS

Paid or volunteer staff members implementing routine testing of inmates in correctional facilities must be certified in HIV counseling, testing, and referral. If rapid HIV testing will be used, the staff member must be trained in the delivery of rapid HIV testing. Staffing levels will vary depending on the number of tests that are required. Depending on the needs of the clients, the abilities of the counselor, and the type of test (rapid or traditional), individual counselors may provide between one and three tests per hour. Providing positive results will take additional time. Agencies should staff their programs according to the projected need for testing at the

correctional facility. This information can be obtained by reviewing the facility's medical procedures, and intake process.

RECRUITMENT

Agencies implementing routine testing of inmates in correctional facilities should work with medical providers at the facility to encourage the promotion of testing during the intake medical appointment. Information flyers distributed during the intake process can facilitate discussions about HIV risk and testing by providers and can serve as a reminder for the provider to refer inmates for CTR. Agencies who choose to partner with correctional facilities to provide this service should document this relationship with a memorandum of understanding that delineates the roles and responsibilities of each partner.

PHYSICAL SETTING CHARACTERISTICS

Routine testing of inmates in correctional facilities can be implemented at any location where confidentiality of clients can be assured (e.g., private area or room) and where a specimen sample can be collected according to minimal standards as outlined by OSHA. Additionally, for rapid testing, the setting must have a flat surface, acceptable lighting, and temperature control (59-80°F).

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement routine testing of inmates in correctional facilities, the following policies and procedures should be in place to protect inmates, the correctional facility and staff, the CBO, and the test provider:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in appropriate language the agency's responsibility and the client's rights. In some states informed consent can be given either verbally or in written form. Inmate participation must always be voluntary and documentation of this informed consent must be maintained in the agency records and in the inmate's medical record if appropriate. Regulations vary by state; therefore, agencies should be familiar with informed consent requirements in their state.

Legal/Ethical Policies: It is important to keep in mind that the routine testing of inmates in correctional facilities requires specialized training and deals with private inmate medical information. Agencies must know their state laws and prison policies regarding who may implement CTR and rapid testing procedures and about disclosure of a client's HIV status (whether positive or negative) to sexual partners, correctional officers, and other third parties. Additionally, some state laws prohibit the disclosure of preliminary positive test results. Agencies must also know, and adhere to all CLIA regulations for testing, documentation, and use of logs relating to test implementation. Finally, agencies are obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, elder abuse, or imminent danger or harm to a specific person.

Facility Regulations: Regulations of correctional facilities are designed for the protection of inmates, staff, and visitors to the facility. It is essential that agencies who wish to partner with a jail or prison understand and follow all rules of the facility.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained. If the referral is within the correctional facility, rules regarding communication between departments must be followed.

Safety: CTR and rapid testing services that are provided in correctional facilities may pose potentially unsafe situations, e.g. the risk of transmitting blood borne pathogens, or concerns about personal safety. Agencies should collaborate with corrections officials to develop and maintain written detailed guidelines for personal safety and security in correctional facilities, for assuring minimal safety standards regarding specimen collection as outlined by OSHA, and to safeguard the security of the data collected, client confidentiality and the chain of custody for testing supplies and collected client specimens.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to clients as necessary. HIV testing providers must know about and have linkage relationships with referral sources for care and prevention interventions/counseling (Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if inmates need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct CTR services, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for counselors and clients and review of the setting should be in place when implementing routine testing of inmates in correctional facilities:

Counselor: Agencies should have a training program in place for all new employees, existing employees and volunteers that will be providing CTR services. This program should ensure that all CTR providers receive adequate training, annual training updates, continuing education and adequate supervision to implement CTR services and the rapid HIV test if appropriate. It should also ensure that CTR providers are skilled and competent in the provision of services by using observed practice of CTR sessions with feedback to counselors and of rapid HIV test procedures if needed. Agencies should have in place a mechanism to assure that all testing protocols are followed as written. QA activities can include observation of sessions as well as role-play demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should assist counselors with intervention delivery and skill development. Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required. For CBOs using rapid HIV test technology, please review the *Procedural Guidance for Rapid Testing in Non-Clinical Settings* in this document.

Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required.

Client: Inmates' satisfaction with the services and their comfort should be assessed periodically. Process monitoring systems should also track the number of referrals made, the number completed, and response to the service. Satisfaction with services may differ if obtained inside the correctional facility compared with services after discharge. Both should be assessed.

Facility: Supervisors should periodically review the testing facility to ensure that a private and confidential setting is available for testing, and that the waiting time for a test does not create a barrier to testing. Feedback should be solicited from correctional officers to ensure that test providers are adhering to the rules and regulations of the facility.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.

- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **II.A-** Percent of newly identified, confirmed HIV positive test results among all tests funded by CDC and reported by your organization.
 - **II.B-** Percent of newly identified, confirmed HIV positive test results returned to clients.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.

KEY ARTICLES AND RESOURCES

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Bureau of Justice Statistics: <http://www.ojp.usdoj.gov/bjs/>

CDC. Revised Guidelines for HIV Counseling, Testing, and Referral.
<http://www.cdc.gov/mmwr/PDF/rr/rr5019.pdf>

CLIA application and requirements: www.cms.hhs.gov/clia
NASTAD Primer on implementing rapid HIV testing:
<http://www.nastad.org/PDF/RAPIDPRIMER.PDF>

National Commission on Correctional Health Care: <http://www.ncchc.org>

Occupational Safety and Health Administration: www.osha.gov

Product information, OraQuick Rapid HIV-1 Antibody Test: <http://www.orasure.com/products/>

Public Health and Corrections Collaboration: <http://www.ncjrs.org/pdffiles/169590.pdf>

Rapid testing: http://www.cdc.gov/hiv/rapid_testing/

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PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF UNIVERSAL HIV TESTING OF PREGNANT WOMEN

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF UNIVERSAL TESTING OF PREGNANT WOMEN

Since the first pediatric case of HIV infection was documented in 1984, tremendous medical and public health achievements have been made in preventing mother-to-child transmission of HIV. A key step toward ensuring that the perinatal HIV interventions offered are effective is to make sure that care providers know the HIV status of the pregnant women in their care. When a woman is identified as HIV infected during pregnancy, antiretroviral and obstetrical interventions can reduce the risk of having an infected baby to $\leq 2\%$. When preventive antiretroviral treatment is not initiated until labor or birth of the newborn, the risk for transmission is 9% to 13%.¹⁻³ Without intervention, the risk for transmission is approximately 25% in the United States.⁴

Maximal reduction of perinatal HIV transmission in the United States depends on ensuring:

- Pregnant women receive prenatal care
- Routine HIV screening of all pregnant women
- Recommended antiretroviral regimens are used during pregnancy and labor and delivery, and after birth for HIV-infected women and their infants, as well as obstetrical interventions for women during labor and delivery
- Routine screening of women during labor and delivery or of the newborn when the mother's HIV status has not been determined previously⁵

Approximately 6,000 to 7,000 HIV-infected women gave birth in the United States in 2000, resulting in an estimated 280 to 370 HIV-infected infants. In about 40% of the perinatal transmissions, health care providers were unaware of the mother's HIV status before delivery. Additionally, in the November 15, 2002, issue of the *Morbidity and Mortality Weekly Report*, CDC published information on the most recently available prenatal HIV testing rates for the United States and Canada.⁶ The report includes a comparison of the HIV prenatal testing rates associated with different testing approaches. In *opt-out*, pregnant women are notified that an HIV test will be included in the standard battery of prenatal tests and procedures and that they may refuse testing. In the more commonly used *opt-in* approach, pregnant women are given pretest counseling and must specifically consent, usually in writing, to an HIV test.

Among states using the *opt-in* approach and in which data were collected from medical records during 1998-1999, testing rates ranged from 25% to 69%. Population-based data from Canada showed testing rates in three *opt-in* provinces of 54% to 83%. In contrast, medical record data

from Tennessee, which uses the opt-out approach, revealed a testing rate of 85%. Data from Canadian provinces using opt-out approaches showed a 98% testing rate in Alberta and a 94% testing rate in Newfoundland and Labrador. At the University of Alabama's 8 prenatal clinics, HIV testing rates rose from 75% to 88% after the opt-out approach was implemented.⁷

CBOs should consider partnering with medical providers who serve women to provide referral services to ensure that the HIV prevention and service needs of both HIV-positive and high risk HIV-negative women and their children are met.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Achieving universal HIV testing of pregnant women involves 6 core elements which include:

- 1) Universal routine prenatal HIV testing in order to minimize perinatal HIV transmission in the United States.
- 2) Routine rapid HIV testing during labor and delivery for women whose HIV status is still unknown.
- 3) Rapid HIV testing post partum for women of unknown HIV status or their neonates, when rapid testing at labor and delivery is not possible or has been previously refused (some states mandate newborn screening in these circumstances).
- 4) Confirmatory testing for all preliminary positive rapid HIV test results.
- 5) When using the rapid HIV test, all standards and procedures related to the use of the rapid test including guidelines for providing preliminary results and obtaining specimens for confirmatory testing are followed (see Procedural Guidance for Rapid Testing in Non-Clinical Settings in this document for additional information on the rapid HIV test).
- 6) For pregnant women who test positive for HIV, facilitate access to appropriate obstetric, medical and social services for prevention, care, and treatment and follow up for her infant.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Universal HIV testing of pregnant women has 6 key characteristics:

- Develop an information sheet with all relevant information regarding HIV prevention counseling, testing, and referral services to be distributed at gynecological appointments and/or during labor.
- Testing is offered on an opt-out basis
- Rescreen all women in high prevalence health care facilities (> 0.5% prevalence among pregnant women) or, in low prevalence facilities, at high risk for HIV infection during the third trimester of pregnancy, or during labor and delivery
- Establish a system to document test results and to track specimens sent for confirmatory testing.
- Develop a system to document and track refusal of HIV testing.
- Work with care provider partners to provide information about the expected public health benefits of the opt-out approach to local representatives of national health care provider organizations, community groups that focus on maternal and child health issues, and state and local government officials

Procedures describe the activities that make up the content of the service and provide direction to agencies or organizations regarding delivery of the service. Procedures achieving universal HIV testing of pregnant women follow:

CBOs should initiate discussions with care providers serving pregnant women about the benefits of routine testing for HIV and of partnering to address routine testing of their patients, the ability of the CBO to provide client-centered counseling without disrupting the flow of the clinic, and ready access to services and referrals for women who test positive. For providers who choose to partner with the CBO, the CBO should work with the state or local health department and the AIDS Education and Training Centers (AETCs) of the Health Resources and Services Administration (HRSA) to facilitate the training of providers to ensure use of the opt-out approach, including documenting HIV test results in a woman's medical chart (if confidential testing is chosen) or the refusal of testing.

In collaboration with medical provider, CBOs should design an information sheet to be given to all untested pregnant women during their medical appointments (informational videos may also be used). The information should describe the risk factors for transmitting or acquiring HIV, features of the HIV antibody test and possible results, the benefits to mother and child of knowledge and treatment of HIV, and HIV prevention, support, and care services available within the community. It should also advise the patient that HIV prevention counseling, testing, and referral is provided as a routine part of the prenatal care, and that patients have the right to refuse the test. This information sheet can be used as a stimulus for the care provider to discuss HIV risk with the woman, and/or to refer her to the CBO representative on site for CTR services. The HIV antibody test may be included in a standard battery of evaluative laboratory tests used. While informed consent is required for HIV testing, if the provider has informed the patient that the test is included in the standard battery and that she can refuse testing, consent for the battery of tests is sufficient. HIV test results or the refusal to be tested should be documented in the woman's medical chart. Fact sheets on HIV testing for providers, an information sheet on HIV and other prenatal tests for women, and forms for documenting HIV test results or refusal are being developed by the American College of Obstetricians and Gynecologists. Working with

ACOG and other partners, CDC has developed a model protocol for implementing rapid HIV testing in labor and delivery settings.

For women attending health care facilities with high HIV prevalence (>0.5%), or, in low prevalence facilities, who are at high risk for HIV infection (e.g., women with HIV-positive partners) testing should be offered a second time if the test was initially refused or if the initial results were negative.

If the woman's HIV status is unknown at the time of labor and delivery, rapid HIV testing should be offered. Again, the patient should be advised of the risk factors for transmitting or acquiring HIV, features of the HIV antibody test and possible results, the benefits to mother and child of knowledge and treatment of HIV, and HIV prevention, support, and care services available within the community. If the rapid HIV test is used to screen for HIV infection all procedures for implementation of the rapid test should be followed (see Procedural Guidance for Rapid Testing in Non-clinical settings for quality assurance related to the rapid HIV test).

Women who test positive at any time during pregnancy or labor and delivery should be informed that medications can be given to her and to her newborn to reduce the chance that the baby will become HIV infected. Women whose test results with the rapid HIV test during labor and delivery are preliminary positive should immediately be offered medication for her and her newborn to reduce the chance that the baby will become HIV infected. Preliminary positive results should be confirmed with a Western Blot confirmatory test.

If the mother's HIV status remains unknown after delivery, rapid HIV testing should be offered for the mother, the infant, or both as soon as possible. Some states mandate newborn screening in this circumstance. CBOs should be aware of their individual state laws.

RESOURCE REQUIREMENTS

Paid or volunteer CBO staff members implementing universal testing of pregnant women must be certified in HIV counseling, testing, and referral. If rapid HIV testing will be used, the staff member must be trained in the delivery of rapid HIV testing. Staffing levels will vary depending on the number of tests that are required. The number of tests completed per hour depends on the needs of the clients, the abilities of the counselor, and the test used (rapid or traditional). Agencies should staff their programs according to the projected need for testing at partner clinics.

RECRUITMENT

Agencies implementing universal testing of pregnant women should work with medical providers at the partner clinics to encourage the promotion of testing during prenatal care visits, during labor and delivery, or in the postpartum period. Information flyers or videos to be used during the prenatal visits can facilitate discussions about HIV risk and testing by providers and can serve as a reminder for the provider to provide testing, or refer for CTR. Agencies who

choose to partner with medical providers to offer this service should document this relationship with a memorandum of understanding that delineates the roles and responsibilities of each partner.

PHYSICAL SETTING CHARACTERISTICS

Universal testing of pregnant women can be implemented at any location where confidentiality of clients can be assured (e.g., private area or room) and where a specimen sample can be collected according to minimal standards as outlined by OSHA. Additionally, for rapid testing, the setting must have a flat surface, acceptable lighting, and temperature control (59-80°F).

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement routine universal testing of pregnant women, the following policies and procedures should be in place:

Informed Consent: Women should be told that HIV testing will be included in the standard battery of prenatal tests and procedures and that she has the right to refuse testing. This information may be included in a consent form that women sign for all prenatal care and services. Specific procedures regarding consent will depend on state and local laws, regulations, and policies. Refusal to be tested should be documented in the woman's medical chart.

Legal/Ethical Policies: It is important to keep in mind that the universal testing of pregnant women requires specialized training and deals with private medical information. Agencies must know their state laws regarding who may implement CTR and rapid testing procedures and about disclosure of a client's HIV status (whether positive or negative) to sexual partners, and other third parties. Additionally, some state laws prohibit the disclosure of preliminary positive test results. Agencies must also know, and adhere to all CLIA regulations for testing, documentation, and use of logs relating to test implementation. Some states require that neonates be screened for HIV if the mother's HIV status is unknown. Agencies and their medical provider partners should be familiar with state laws regarding this requirement. Finally, agencies are obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Safety: CTR and rapid testing services may pose potentially unsafe situations, e.g. the risk of transmitting blood borne pathogens. Agencies should develop and maintain written detailed guidelines for assuring minimal safety standards regarding specimen collection as outlined OSHA, and to safeguard the security of the data collected, client confidentiality and the chain of custody for testing supplies and collected client specimens.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to clients as necessary. Providers must know about and have linkage relationships with referral sources for HIV and ongoing gynecological care as well as prevention interventions/counseling (Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if clients need additional assistance in decreasing risk behavior. In addition, agencies must provide necessary referrals for infants exposed to HIV.

Volunteers: If the agency is using volunteers to assist in or conduct CTR services, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for counselors and clients and review of the setting should be in place when implementing universal testing of pregnant women:

Counselor: Agencies should have a training program in place for all new employees, existing employees and volunteers that will be providing CTR services. This program should ensure that all CTR providers receive adequate training, annual training updates, continuing education and adequate supervision to implement CTR services and the rapid HIV test if appropriate. It should also ensure that CTR providers are skilled and competent in the provision of services by using observed practice of CTR sessions with feedback to counselors and of rapid HIV test procedures if needed. Agencies should have in place a mechanism to assure that all testing protocols are followed as written. QA activities can include observation of sessions as well as role-play demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should assist counselors with intervention delivery and skill development. For CBOs using the rapid HIV test control kits, available from OraSure Technologies, should be used to ensure reliability and validity of the test

process and materials. CDC also offers the *Model Performance Evaluation Program* to ensure accurate testing as a basis for development of prevention and intervention strategies. (For QA activities related to rapid HIV testing, please review the Procedural Guidance for Rapid Testing in Non-clinical Settings)

Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required.

Client: Clients' satisfaction with the services and their comfort should be assessed periodically. Process monitoring systems should also track the number referrals made and completed as well as response to the service.

Facility: Supervisors should periodically review the testing facility to ensure that a private and confidential setting is available for testing, and that the waiting time for a test does not create a barrier to testing. Feedback should be solicited medical to ensure that test providers are integrated appropriately into the clinic setting.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.

KEY ARTICLES AND RESOURCES

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PRAMS website: http://www.cdc.gov/nccdphp/drh/srv_prams.htm

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SECTION 3: Prevention Interventions for People Living with HIV and Persons with Negative or Unknown Serostatus at Very High Risk

Activities included in this section are intended to help agencies target HIV risk reduction for persons living with HIV (PLWH) and persons with negative or unknown serostatus at very high risk for infection. Persons living with HIV may need different prevention interventions over the course of their infection with needs upon initial diagnosis differing from those years later.

Persons at very high risk for HIV, defined as someone who, within the past 6 months, has had unprotected sex with a person who is living with HIV; unprotected sex in exchange for money or sex; multiple (greater than 5) or anonymous unprotected sex or needle-sharing partners; or has been diagnosed with a sexually transmitted disease, may also need interventions that differ in intensity, depending on their circumstances. Persons with unknown or negative serostatus who have not been tested in the past 6 months, should be offered HIV counseling and testing.

Section 3, Part A: Prevention for Individuals Living with HIV and Their Sex or Injecting Drug- Using Partners Who Are HIV Negative or Unaware of Their HIV Status

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF PREVENTION CASE MANAGEMENT (PCM) FOR PERSONS LIVING WITH HIV

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF PCM FOR PERSONS LIVING WITH HIV

Prevention Case Management (PCM) is a client-centered HIV prevention activity with the fundamental goal of promoting the adoption and maintenance of HIV risk-reduction behaviors by clients with multiple, complex problems and risk-reduction needs.^{1,2} PCM provides client-centered, multiple-session HIV risk-reduction counseling to help individuals initiate and maintain behavior change to prevent the transmission of HIV while addressing competing needs which may make HIV prevention a lower priority. This HIV prevention activity addresses the relationship between HIV risk and other issues such as substance abuse, mental health, social and cultural factors, and physical health.

As a hybrid of HIV risk-reduction counseling and traditional case management for people living with HIV (PLWH), PCM provides intensive, on-going, individualized prevention counseling, support, and service brokerage. Priority for PCM services should be given to HIV seropositive persons having or likely to have difficulty initiating or sustaining practices that reduce or prevent HIV transmission and reinfection. PCM involves the coordination of primary and secondary prevention interventions and often involves close collaboration with Ryan White CARE Act (RWCA) case management providers. PCM services might include traditional risk-reduction topics such as abstinence, decreasing the number of sexual/needle-sharing partners or increasing condom use, as well as other subjects including medication adherence or taking an active role in medical care. Further, PCM ensures referral to needed medical and psychosocial services affecting risk behavior, including mental health and substance abuse treatment services as well as diagnosis and treatment of sexually transmitted diseases (STDs).

CORE ELEMENTS, KEY CHARACTERISTICS AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. PCM has 6 core elements which include:

- 1) PCM is a hybrid of HIV risk-reduction counseling and traditional case management.
- 2) PCM is based on the premise that some people may not be able to prioritize HIV prevention when they face problems perceived to be more important and immediate.
- 3) PCM is intended for people living with HIV (PLWH) with multiple, complex problems and risk-reduction needs who are having, or are likely to have difficulty initiating or sustaining practices that reduce or prevent HIV transmission.
- 4) Individuals who are committed to participating in ongoing risk-reduction counseling should be targeted with PCM.
- 5) Organizations must hire case managers with the appropriate training and skills to complete the PCM activities within their job description.
- 6) Clear procedure and protocol manuals for the PCM program must be developed to ensure effective delivery of PCM services and minimum standards of care.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. PCM has 8 key characteristics:

- Develop a client recruitment and engagement strategy.
- Screen and assess clients to identify those who are at highest risk and are appropriate for PCM.
- Develop a written, client-centered prevention plan.
- Provide multiple HIV risk-reduction counseling sessions.
- Provide active coordination of services with follow-up. Agency protocols should address co-managing clients with RWCA case managers to avoid duplication of services.
- Monitor and reassess clients' needs, risks, and progress.
- Establish protocols to classify clients as "active," "inactive," or "discharged," and outline the minimum active effort required to retain clients.
- Discharge clients from PCM upon attainment and maintenance of risk reduction goals.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for PCM follow:

When a new client is introduced to the PCM program, providers should ensure that the reason for the referral, the role of the PCM program, and the role of the provider are understood. Written, informed consent describing all relevant policies and procedures (including the confidential and voluntary nature of the service) and a commitment to participate in ongoing risk-reduction counseling should be obtained. Clients should be provided a copy of this consent, and the original should be maintained in an individual client record. Each client should have an

individual confidential file, and all records should be kept in a locked file cabinet with access limited to the prevention case manager and his/her immediate supervisor.

All clients must be screened for eligibility for services. Appropriate screening procedures should be developed to identify persons at highest risk for transmission or acquisition of HIV. Assessment instruments should address HIV and STD transmission risks, substance use/abuse, and medical and psychosocial needs. Care should be taken to ensure that the assessment is conducted in a culturally appropriate manner.

After completion of the assessment, the PCM provider and the client should collaborate on the development of a prevention plan which is then signed by the client and provider. The plan should outline and define risk-reduction behavioral objectives and strategies for behavioral change. In addition to risk reduction goals, the plan for HIV-positive clients should include referral to appropriate medical care if needed and should address adherence to retroviral medication, if appropriate. PCM providers should coordinate with the RWCA case manager, where possible to provide the best possible constellation of services. The plan must also include referral for evaluation and treatment of STDs, TB, hepatitis and other related health concerns at regular intervals. It should address referral for substance abuse treatment, if necessary. Partner counseling and referral services (PCRS) should also be addressed in the prevention plan. Finally, plans for referral follow-up should be outlined.

When risk behaviors have been identified and appropriate risk-reduction strategies have been outlined, prevention case management sessions begin. Multiple counseling sessions are aimed at meeting the identified behavioral objectives. These sessions may include education, skill development, role-play, support, or other techniques. Client notes should be filed after each session indicating, at a minimum, the goal addressed during the session, progress toward the goal, barriers to implementation of behavior change and the way these are or will be addressed, referrals made with plans for follow-up, and a plan for the next session.

PCM providers should ensure active coordination of services with follow-up to avoid duplication of services (e.g., agency protocols should address co-managing clients with RWCA case managers). If referrals are to be made as a part of the prevention plan, the agency should have a standardized written referral process. A system should be in place to ensure availability and access to these referrals and to track their completion. This system might include formal or informal agreements including memoranda of agreement with relevant service providers. Written informed consent from the client for sharing client information should be obtained before communication between agencies begins. Medical and psychological services should be available if emergencies arise, and referral agreements for these services should be in place before initiating PCM. Current referral and access information for all community providers should be maintained.

Ongoing needs assessment is essential to monitor progress toward PCM goals and to monitor changing needs of the client. Prevention plans must be updated to reflect any change. Upon attainment and maintenance of the objectives of the plan, a determination should be made by the client and the PCM provider that the client is ready for discharge from PCM. Agencies

implementing PCM must have discharge protocols in place to ensure that discharged clients are connected to needed services and resources, and a return to PCM is available, if needed.

RESOURCE REQUIREMENTS

Because PCM is an intervention with a great deal of overlap with mental health services, providers must have experience in managing mental health issues (a licensed counseling or mental health provider is preferred). Staffing levels for PCM will vary according to the number of clients that an agency expects to serve and the availability of other services in the area. In areas with limited referral sources, the PCM provider will be expected to meet multiple needs for his/her clients. To meet these needs, it will be necessary to reduce the case load for individual providers. In resource-rich areas, more service needs can be met by referral and a PCM provider can be expected to carry a larger caseload. Programs should consider the number of clients to be served, the needs of those clients and the services available in their area when determining staffing levels needed, but a typical caseload will include approximately 15-20 clients for each 1.0 full-time equivalent (FTE) PCM provider.

RECRUITMENT

PCM programs rely upon referrals and recruitment to establish a client base. To enlist clients for PCM, programs should be located in a setting that offers other services for PLWH. In this setting, clients can be referred from existing services that the program offers, such as outreach, counseling and testing services, Ryan White case management, medical care, STD assessment and treatment, substance abuse treatment, or mental health services to PCM. If these services are not offered on site, referral agreements from agencies providing these services should be established. Incentives (e.g., bus tokens, hygiene kits, t-shirts) can be used to increase participation.

Agencies wishing to implement PCM should review the Procedural Guidance for Recruitment (see p. 11) in order to choose a recruitment strategy that will work in the setting in which they plan to implement PCM.

PHYSICAL SETTING CHARACTERISTICS

Agencies implementing PCM should choose a location that is easily accessible from public transportation routes. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room, or outside noise levels. It may be necessary for providers to meet clients outside of an office setting. In this case, efforts should be made to secure a location that will ensure the confidentiality of the client and minimize distractions and interruptions. Regardless of where actual PCM sessions occur, the agency implementing the intervention must ensure that all records are maintained in a locked file cabinet or in a secured computer workstation.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement PCM the following policies and procedures should be in place to protect participants, the agency, and the Prevention Case Manager:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that PCM is an intervention that deals with disclosure of HIV status. Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants, as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior. All persons screened for PCM, regardless of eligibility, should be offered counseling by a prevention case manager and referrals relevant to their needs.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both providers and participants should be in place when implementing PCM:

Provider: Providers of PCM services should have experience working in the fields of mental health services and HIV prevention (a licensed counseling or mental health provider is preferred). Agencies should have in place a mechanism to ensure that all sessions address the prevention plan. Quality assurance activities can include observation or review of sessions with key staff and supervisors involved with the activity. This review should focus on the quality of and appropriate adherence to the prevention plan, accessibility and responsiveness to expressed client needs, and important process elements (e.g., time allocation, clarity). PCM providers should meet at least monthly with either a direct supervisor or with a peer supervisor. Selected intervention record reviews should focus on ensuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at regular intervals established by the agency. Process monitoring systems should also track the number of sessions each participant attends, as well as reasons for non-attendance.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:

- **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).
- **III.A-** Proportion of persons living with HIV, their sex partners and injection drug-using contacts who are HIV negative or who do not know their HIV status who completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
- **III.C** Percent of HIV infected persons who, after a specified period of participation in each of the prevention interventions supported by the program announcement, report a reduction in sexual or drug-using risk behaviors or maintain protective behaviors with seronegative partners or with partners of unknown status.
- **IV.A** Proportion of client records with the CDC-required demographic and behavioral risk information.
- **V.A** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

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UCSF, AIDS Policy Research Center, Prevention with Positives Resources

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF INTEGRATING PREVENTION SERVICES INTO MEDICAL CARE FOR PEOPLE LIVING WITH HIV

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF THE INTERVENTION

After testing positive for HIV, many people decrease behaviors that may transmit HIV to others.^{1,2} However, recent studies suggest that such behavioral changes are not maintained by all HIV-infected persons and that some continue to engage in behaviors that place others at risk for HIV infection.^{3,4} The HIV outpatient clinic is an ideal, yet underutilized, setting to (a) reach a large number of seropositive individuals who regularly visit the clinic for treatment; (b) implement a safer-sex prevention program to instill self-protective and partner-protective motivations for reducing risk behaviors across time; (c) integrate prevention with routine medical care; and (d) involve clinic staff, especially physicians, physicians assistants, nurses, nurse practitioners, and counselors, in prevention counseling. Recognizing the importance of including HIV prevention in the medical care setting, the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the National Institutes for Health (NIH), and the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA) recently published recommendations for incorporating HIV prevention into the medical care of persons living with HIV.⁵

The CDC/HRSA/NIH/HIVMA of the IDSA recommendations state that clinicians can greatly affect patients' risks for transmission of HIV to others by:

- Performing a brief screening for HIV transmission risk behaviors
- Communicating prevention messages
- Discussing sexual and drug-use behavior
- Positively reinforcing changes to safer behaviors
- Referring patients for such services as substance abuse treatment
- Facilitating partner notification, counseling, and testing
- Identifying and treating other sexually transmitted diseases (STDs)⁵

These recommendations are integrated into three major components:

- Screening for HIV transmission risk behaviors and STDs
- Providing brief behavioral risk-reduction interventions in the office setting and referring selected patients for additional prevention interventions and other related services

- Facilitating notification and counseling of sex and needle-sharing partners of infected persons⁵

The recommendations for incorporating prevention services into medical care are intended for all persons who provide care services to people living with HIV (PLWH) (e.g., physicians, nurse practitioners, nurses, physician assistants). This also includes, and would be appropriate for community-based organizations (CBOs) that provide medical care services. However, CBOs that do not provide care may choose to partner with care providers to offer a range of services including brief prevention messages delivered by the care provider as well as more traditional prevention services (e.g., Prevention Case Management, Partner Counseling and Referral Services, Counseling Testing and Referral for partners) that could be available on-site at the clinic.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Integrating prevention into medical care has 7 core elements that include:

- 1) Adopt prevention as a standard part of clinical practice.
- 2) Conduct a brief assessment (risk screening) of behavioral and clinical factors associated with transmission of HIV and other STDs.
- 3) Identify patients at greatest risk for transmission of HIV who should receive more in-depth risk assessment and HIV risk-reduction counseling, other risk-reduction interventions, or referral for other services.
- 4) Deliver brief (3-5 minute) prevention messages focused on self and/or partner prevention and HIV status disclosure to every patient at every clinic visit.
- 5) Screen for and treat STDs, as appropriate.
- 6) Discuss reproductive health options with female patients of childbearing age.
- 7) Hang waiting and exam room posters and hand out patient brochures that present education and prevention messages and reinforce messages delivered by the clinician.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. Integrating prevention into medical care has 5 key characteristics:

- Screening methods include probing for behaviors associated with transmission of HIV and other STDs, eliciting patient reports of symptoms and other STDs, and laboratory testing for other STDs.
- Training for all clinic staff should include information on the use of open-ended questions, demonstrating empathy and remaining non-judgmental.
- Counseling sessions can last longer than 5 minutes and follow-up reminders may last less than 3-5 minutes depending on the needs of the patient. It is important to repeat the message over time.
- Providers need to deliver prevention messages at all clinic visits; however, these messages may be eliminated if pressing medical needs take priority.
- Clinics should make condoms available in a way that patients can feel comfortable taking them as needed.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for integrating prevention into medical care follow.

Incorporating prevention into a busy clinic can be difficult, but can be facilitated with some modification of the clinic structure and flow. Creating an atmosphere that endorses an integrated approach demonstrates that prevention of HIV is important to the clinicians and staff. Posting prevention messages in the waiting area and in examination rooms and giving every patient printed material related to HIV prevention reminds the clinician to address prevention, and prepares the patient to discuss these issues.

Prescreening patients prior to the medical appointment using pencil-and-paper surveys, audio-, video-, or computer-assisted questionnaires, or brief interviews with non-medical staff can provide the clinician with information that he/she can use to understand patients' risk factors and symptoms of STDs, if present, and to elicit more in-depth discussions of HIV prevention during the medical visit. If the patient reports engaging in risky behaviors (unsafe sex or injection practices) the clinician should provide an appropriate brief prevention message. This message may include a general prevention message, a tailored message which addresses specific patient behaviors or concerns, and messages that correct misconceptions about risk or reinforce steps the patient has already taken to decrease the risk of HIV transmission. Prevention messages should stress to patients that abstinence or sex with a partner of concordant serostatus are the only ways to ensure that HIV is not transmitted. However, patients should also know that sex with concordant partners does not protect against other STDs or reinfection with HIV. For sexually active patients, condom use is the safest means of preventing transmission or acquisition of HIV or other STDs. Patients should also be made aware of the importance of disclosure of their HIV status to potential sex partners.

Because the presence of an STD can dramatically increase the transmissibility of HIV and the progression of HIV disease, the clinician should also recommend diagnostic testing and treatment, as appropriate, for STDs for patients engaging in unsafe sexual behaviors. These tests should be recommended at the first visit for all patients, at least yearly for sexually active patients, and more frequently for patients at high risk. Patients should receive testing for STDs if

they report any symptoms of infection, regardless of reported sexual behavior or other epidemiologic risk information.

In addition, because the risk for perinatal HIV transmission is high without appropriate intervention, clinicians should assess whether women of childbearing age might be pregnant, are interested in becoming pregnant, or are not specifically considering pregnancy, but are sexually active and not using reliable contraception. Referral for reproductive health issues and counseling may be appropriate.

The clinician should also refer the patient for more extensive prevention intervention or to other services that may benefit the patient and/or his or her partner as needed (e.g., substance abuse treatment services, mental health services, medication adherence counseling, PCRS). Referral follow-up can provide the clinician with information about the success of the referral, patient satisfaction with the referral, or barriers to completing it. This information can be used to compile a referral guide for use by all clinic providers.

Finally, clinicians should recognize that risk is not static. Patients' lives and circumstances change, and their risk of transmitting HIV may change from one medical encounter to another. Screening and providing risk-reduction messages should occur at every medical visit unless pressing medical issues take precedence.

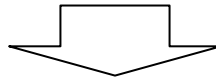
Materials that are helpful for introducing the concept of integrated prevention and care services include:

- *Posters*, in languages appropriate to the populations served, with the general prevention messages to hang in clinic waiting areas and hallways
- *Brochures*, in languages appropriate to the populations served, given to patients when they register at the front desk. The brochures should emphasize the role of STDs in HIV transmission and the need to be tested and treated for STDs at the first sign or suspicion of symptoms, the potential role of drug use in increasing risky behaviors, the risks of unsafe sex or injection practices for patients and their partners even in the presence of a low or undetectable viral load, as well as messages about the importance of disclosure.
- *Exam room posters*, in languages appropriate to the populations served, which contain the same messages as the brochure.
- *Documentation of patient counseling* which may include such methods as a chart sticker, a stamp, or a check box in the printed or electronic medical record. The purpose is to remind the provider to do the counseling regularly.
- *Additional supportive materials* given out as a supplement to the brochure at subsequent visits. Materials can address additional prevention topics of interest, and may include helpful information and testimonials related to changing behavior.

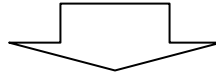
One model for integrating prevention into care is diagrammed below.

Patient is given a language appropriate brochure or flyer by front desk staff and asked to read it before seeing the medical provider. Patient reads the materials while waiting

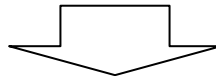
and notices the prevention posters in the waiting room.



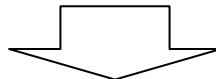
Patient goes into exam room and notices a small poster on the exam room wall that reinforces the messages that are in the brochure.



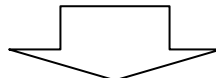
Provider conducts the usual medical exam.



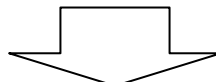
At the end of the medical exam the provider conducts a brief 3-5 minute intervention. Provider reviews the information gained in the pre-appointment survey and asks clarifying questions. Provider gives a brief prevention message targeted to the needs of the patient.



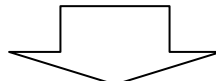
Provider uses the brochure, exam room poster, or other prevention materials to facilitate counseling. Provider or patient checks behaviors noted in the brochure and sets goals for behavior change. Provider documents counseling in the patient's chart.



If needed, the provider gives appropriate referrals to the patient. Provider tells patient that he/she is interested in hearing how it is going next time the patient comes in for an appointment.



Patient leaves feeling cared about, better informed about safer sex and disclosure practices, and motivated to practice safer behaviors.



For follow-up visits, provider inquires about progress on goals set and referrals, if given at last visit. Provider reinforces healthful behavior and helps patient find ways to overcome obstacles. Provider and patient re-establish goals for next time.

CBOs that do not provide medical care can partner with a medical provider to assist with the creation of prevention messages and materials that are appropriate for the clinic setting, and with

training and prevention strategies for clinics. CBOs can also assist clinics in providing and facilitating referrals and by providing more extensive prevention services to those clients with additional prevention needs.

RESOURCE REQUIREMENTS

Integrating prevention into medical care uses existing providers and clinic staff and asks that providers spend 3 to 5 minutes discussing safer sexual behavior and disclosure with their patients during each clinic visit. No new staffing is required, although each clinic should appoint a nurse or physician assistant (0.5 full-time equivalent [FTE]) as a prevention coordinator to coordinate training and ensure that materials are available and staff are implementing the intervention. The major expenses to clinics are materials (e.g., training materials, posters, brochures, chart stickers, anatomical models, condoms, and lubricant) and release time for each provider and clinic staff to attend training.

RECRUITMENT

Because agencies who choose to integrate prevention into their medical care as recommended by the CDC/HRSA/NIH/HIVMA of the IDSA guidelines will offer prevention services as the standard of care in their clinics, no specific strategy for recruitment is endorsed; all clinic patients receive the intervention with appropriate messages delivered at each appointment. However, all patients should be informed that the clinic has adopted a model of integrated service so that they may make an informed choice regarding their attendance at the clinic.

PHYSICAL SETTING CHARACTERISTICS

Sites must be HIV-outpatient health care clinics. Sites should be those where there is clinic-wide support for this intervention, with a commitment to training in incorporating prevention messages, communicating with patients about sex and drug use behavior, understanding prevention interventions and factors related to risk behavior, and knowledge of community resources available by referral. Clinics should have private examination rooms where providers can talk confidentially with patients about their sexual behaviors.

NECESSARY POLICIES AND STANDARDS

Before a clinic attempts to integrate prevention into its medical care, the following policies and procedures should be in place to protect participants, and the clinic:

Informed Consent: All clinic patients should be informed that addressing issues of sexuality and HIV prevention is part of the standard of care at the clinic that integrates prevention into medical care. As with any patient care issues, they have the right to refuse treatment.

Legal/Ethical Policies: It is important to keep in mind that by virtue of participation in this intervention, clients will be disclosing their HIV status. Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that the confidentiality of clinic patients is maintained.

Data Security: Agencies must have a data handling policy that will ensure patient confidentiality and the confidentiality of chart notes and intervention reminders.

Cultural Competence: Agencies must strive to offer culturally competent services by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers when possible, or translation should be available, as appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care*, which should be used as a guide for ensuring cultural competency in programs and services

Referrals: Clinics must be prepared to supply appropriate referrals to patients, as necessary. Providers must know about referral sources for prevention interventions/counseling (PCM, PCRS, health department/CBO programs for prevention interventions with PLWH) if patients need additional assistance in decreasing risk behavior.

Clinic Support: Clinic management must demonstrate support for integrating prevention into care by:

- Encouraging staff attendance at one training related to providing prevention services (i.e., providing paid time off to attend, and promoting the training)
- Obtaining, distributing, and maintaining prevention materials
- Committing to patient counseling delivered by primary care providers, and allowing providers the time to deliver prevention messages at every visit

QUALITY ASSURANCE

Quality assurance activities for clinics, providers, and patients should be in place when integrating prevention into care to ensure fidelity to the core elements of the service. These include the following:

- 1) *Chart Audits* to ensure that providers are delivering and noting the delivery of prevention messages.
- 2) *Provider Surveys* to assess skill in eliciting behavioral information, providing prevention messages, attitudes and beliefs about the provider's role in delivering prevention messages, frequency of message delivery, and satisfactions with the intervention.
- 3) *Patient Satisfaction* should be monitored.
- 4) *Observation* of the clinic by the clinic coordinator to ensure that materials are maintained in the waiting room and exam rooms and that patient brochures and informational flyers are handed out to all patients.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements
- Collect and report data consistent with CDC requirements to ensure data quality and security, and client confidentiality
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects, upon request

KEY ARTICLES AND RESOURCES

¹ Valleroy LA, MacKellar DA, Karon JM, Rosen DH, McFarland W, Shehan DA, Stoyanoff SR, LaLota M, Celentano DD, Koblin BA, Thiede H, Katz MH, Torian LV, Janssen RS. HIV prevalence and associated risk in young men who have sex with men. JAMA 2000;284:198-204.

² Allen S, Serufilira A, Bogaerts J, Van de Perre P, Nsengumuremyi F, Lindan C, Carael M, Wolf W, Coates T, Hulley S. Confidential HIV testing and condom promotion in Africa: Impact on HIV and gonorrhea rates. JAMA 1992;268:3338-43.

³ Centers for Disease Control and Prevention (CDC). Resurgent bacterial sexually transmitted disease among men who have sex with men — King County, Washington, 1997 – 1999. MMWR 1999;48:773-7.

⁴Crepaz N, Marks G. Towards an understanding of sexual risk behavior in people living with HIV: A review of social, psychological, and medical findings. *AIDS* 2002;16:135-49.

⁵CDC. Incorporating HIV prevention into the medical care of persons living with HIV: Recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medical Association of the Infectious Diseases Society of America. *MMWR* 2003; 52(RR-12); 1-24.

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF TEENS LINKED TO CARE

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF TEENS LINKED TO CARE

Teens Linked to Care (TLC)¹⁻⁴ is an effective intervention for young people (ages 13 to 29) living with HIV and is delivered in small groups using cognitive-behavioral strategies to change behavior. Manuals, training materials, and training in the conduct and supervision of the intervention will be available from University of California at Los Angeles. A complete copy of the TLC intervention is located at <http://chipts.ucla.edu/interventions/manuals/>.

The intervention is based on Social Action Theory,⁵ which emphasizes how contextual factors influence an individual's ability to respond effectively to stressful situations, solve problems, and act effectively to reach goals. This theory was chosen based on qualitative study and other intervention research with disenfranchised young people, a majority of whom were people of color.⁶⁻⁹

Antiretroviral therapies have extended the length and quality of life for people living with HIV. Therefore, there is a need for ongoing support for maintaining behavioral changes over time. This program is designed to be implemented over a long period of time or over a two-to-three-month period, depending on staffing constraints and participants' preferences. The program can be offered on an ongoing basis, with multiple points of entry (drop-in) for young people over time. Alternatively, the program can be linked to medical care appointments. For example, when agencies have scheduled all persons living with HIV on a specific day, the program can be delivered in conjunction with treatment. Finally, by offering a large number of sessions, the program allows young people to drop-into maintenance sessions without finding redundant content.

TLC consists of three modules, each of which consists of 8-12 sessions that are delivered in a general sequence, with flexibility as to delivery and scheduling of sessions and multiple points of entry into the ongoing program by participating young people. Each module is focused on a different behavioral outcome:

Module I: *Staying Healthy* targets health care utilization and health behaviors. The module has been shown to increase the number of positive lifestyle behaviors and use of positive action coping styles in young women, and use of the social support coping style in young people of both sexes.

Module II: *Acting Safe* addresses both sexual and drug-use-related transmission acts. Research indicates that young people who attended the intervention reported fewer partners, fewer HIV-negative partners, and fewer unprotected sex acts. Additionally, youth attending the intervention reported significant reductions in a weighted substance use index, prevalence of alcohol/marijuana use, and the use of illicit drugs.

Module III: *Being Together* focuses on improving quality of life. In research, group members reported decreases in feelings of distress, physical symptoms of distress, generalized anxiety, and fear-based anxiety.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Teens Linked to Care has 4 core elements, which include:

- 1) The delivery of three modules. Each focuses on a different set of outcomes and includes 8-12 sessions, described below in **Content** and **Format** and structured in the theoretical model, which includes:
 - a. Review of previous goals
 - b. Activity focused on skills or attitude development or knowledge acquisition
 - c. Reframing of negative behavior patterns
 - d. Reinforcement of desired behavior using incentives
 - e. Setting of new goals
- 2) Delivery of modules in highly interactive small groups.
- 3) Exercises in each session that are constructed to be meaningful personal experiences, leading to increased skills and development of the attitudes and knowledge needed to support the acquisition of new behaviors.
- 4) Individualized homework tasks assigned following each session.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. TLC has 4 key characteristics:

- Groups may have between 3 and 13 members.
- Small group participants of similar ages are ideal, but groups can be comprised of individuals of different ages. Facilitators should tailor messages appropriate to the age group attending and the levels of development.

- Each session contains approximately six exercises or different activities.
- Participants should attend all sessions of the intervention, with flexibility for participants to drop into particular sessions on their own schedule.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for Teens Linked to Care follow.

Sessions: While the process of change is the same in each session, the content differs between sessions and was based on findings from qualitative research into what young people living with HIV think is important.

The following is a list of session topics by module:

Content:

Staying Healthy:

- Sessions 1 & 2: I'm HIV Positive--Attitudes Towards Living with HIV and Exploring Future Goals
- Session 3: Disclosure--Should I Tell Others My Status?
- Session 4: Coping with Stigma
- Session 5: Wanting to Stay Healthy
- Session 6: How Do I Use Drugs and Alcohol?
- Session 7: What Am I Going to Do about Substance Abuse?
- Session 8: Preventing Re-infection
- Session 9: Staying Calm
- Session 10: Attending Health Care Appointments
- Session 11: Taking Prescribed Medications
- Session 12: Participating in Medical Care Decisions

Acting Safe:

- Session 1: Should I Protect Myself and My Partner?
- Session 2: Which Protection Methods and Sex Acts Are Best for Me?
- Session 3: Should I Tell My Partner I Am HIV-Positive?
- Session 4: Should I Try To Get My Partner to Accept Our Using Condoms?
- Session 5: Should I Refuse Unprotected Sex?
- Session 6: Establishing the Commitment
- Session 7: How Can I Stop Drug and Alcohol Thoughts?
- Session 8: How Can I Avoid External Triggers?
- Session 9: How Can I Avoid Internal Triggers?
- Session 10: How Can I Handle Anxiety and Anger?
- Session 11: How Can I Handle Drugs, Alcohol, and Sex?

Being Together:

- Session 1: How Can I Have a Better Quality of Life?
- Session 2: How Can I Reduce Negative Feelings?
- Session 3: Who Am I?
- Session 4: Is What I See the Real Thing?
- Session 5: What Direction Should I Follow?
- Session 6: How Can I Be a Good Person?
- Session 7: How Can I Get Wise?
- Session 8: How Can I Care about Others?

Format: A small group of HIV-positive young people meet regularly to provide social support, learn and practice new skills, and to socialize. At the beginning of each session, participants review their progress toward achieving their goals. Young people are complimented and compliment each other for trying to change their lives. In the middle of each session, facilitators focus participants on skill development, attitude formulation, knowledge acquisition, and/or reframing of previous dysfunctional behavior patterns. A series of fun activities are used to accomplish this goal. Participants may videotape themselves meeting a new friend, disclosing their serostatus, or brainstorming on how to get angry with a doctor without then receiving poor medical care. New goal-setting occurs at the end of each session, and compliments are shared by all group members.

Mechanism of Behavior Change: This program helps HIV-positive young people identify ways to improve their quality of life within specific areas, by setting new habits and daily social routines. Young people set goals around their health, their sexual relationships, drug use, and daily peace. Once goals are set, the group helps each person set realistic ways to meet these goals and helps to solve problems related to reaching the goals. The steps of problem solving include:

- 1) Determining what you want.
- 2) Identifying ways to get what you want.
- 3) Evaluating the best way to get what you want.
- 4) Practicing how to get what you want.
- 5) Trying to get what you want.
- 6) Reviewing how successful you were in reaching your goal.

Participants not only work on their own goals, but role-play assisting other young people to reach their goals (e.g., a new job, a change in their living arrangements, education, or social relationships). At the end of every TLC session, participants agree on the next week's plans to improve their lives. Improving the quality of life, meditation, and focused attention skills are part of TLC.

Summary: Every session in each of the three TLC modules establishes a routine to help participants confront a specific attitude or belief, address thoughts and feelings, and/or change a specific behavior. As such, community agencies that implement TLC must include the following core components in each session in order for the intervention to be effective:

- Participants **review previous goal.**
- Facilitator provides **engaging activities focused on: problem-solving, attitude formulation, knowledge acquisition, and/or skill development.**
- Facilitators help participants to **reframe negative behavior patterns.**
- Facilitators **reinforce desired behavior through use of incentives.**
- Participants **set a new goal.**

Materials used to deliver and/or reinforce the intervention include hand cards, tokens, a feeling thermometer, participant workbooks, and a facilitator manual. Most of these items are available for download at the intervention website (see the end of this section). Role playing is used to demonstrate the relevant concepts or issues.

RESOURCE REQUIREMENTS

The resources needed are contingent upon the number of people living with HIV who are served in the agency. For an agency serving up to 200 people living with HIV, a desirable staffing pattern for an agency would be to hire a program supervisor (50% full-time equivalent [FTE]) for the first year to train, supervise, and coordinate implementation during the first year. This person should have experience in behavioral theories of change and experience in conducting interventions with persons in small groups. For the program delivery, one option is to train all counselors within an agency in the model and to offer drop-in groups at several different times during a week for people living with HIV. One group would be offered at night, one during the day, and one during the weekend. Therefore, there needs to be flexibility in the staffing pattern, with full time staff who are willing to adjust their schedules to the needs of clients. Each small group will require about 25% FTE per week of a counselor to deliver the program. One full-time (or FTE) should be able to provide the program to 50-70 people living with HIV at any one time. The counselor or case manager delivering the program must also have skills in managing interactions within small groups and behavioral and cognitive-behavioral, skills-building approaches to interventions. The desirable staffing pattern is to train all counselors within a case management service or a counseling service and to utilize about 25% of each counselor's time to deliver the program (excluding supervisory time). A TV and a VCR will be needed to deliver the program, as well as small items such as condoms, demonstration models, and standardized program workbooks. Four trainings of four days each are needed for program supervisors at intervals of one to two months apart. These supervisors may then be charged with training all staff within the agency.

RECRUITMENT

Young people living with HIV can be recruited for TLC from a variety of sites: community venues, AIDS service organizations, or medical clinics. Young people can also be recruited through word-of-mouth, print advertisements, or flyers. Agencies wishing to implement TLC should review the Procedural Guidance for Recruitment (see p. 11) in order to choose a recruitment strategy that will work in the setting in which they plan to implement TLC.

PHYSICAL SETTING CHARACTERISTICS

TLC can be implemented at any location where the confidentiality of participants can be ensured (e.g., a private room) and an agency is able to assemble a group of young people living with HIV who wish to participate in the intervention.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement TLC the following policies and procedures should be in place to protect participants, the agency, and the TLC intervention team:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that by virtue of participation in TLC, clients will be disclosing their HIV status. With that in mind agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to

these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants, as necessary. Providers must know about referral sources for prevention interventions/counseling (Prevention Case Management, Partner Counseling and Referral Services, Health Department/Community-based Organization programs for prevention interventions with PLWH) if clients need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both facilitators and participants should be in place when implementing TLC:

Facilitator: Training for facilitators should address the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practice of mock intervention sessions. Agencies should have in place a mechanism to ensure that all session protocols are followed as written. QA activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on adherence to session content, use of key cognitive behavioral skills techniques; accessibility and responsiveness to expressed participant needs; and important process elements (e.g., time allocation, clarity, use of social rewards). Selected intervention record reviews should focus on assuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at the final session of each module. Process monitoring systems should also track the number of sessions each participant attends, as well as reasons for non-attendance.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **III.A-** Proportion of persons living with HIV, their sex partners and injection drug-using contacts who are HIV negative or who do not know their HIV status who completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
 - **III.C-** Percent of HIV infected persons who, after a specified period of participation in each of the prevention interventions supported by the program announcement, report a reduction in sexual or drug-using risk behaviors or maintain protective behaviors with seronegative partners or with partners of unknown status.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information

KEY ARTICLES AND RESOURCES

¹Rotheram-Borus MJ, Lee MB, Murphy DA, Futterman D, Duan N, Birnbaum J, and the Teens Linked To Care Consortium. (2001). Efficacy of a preventive intervention for youth living with HIV. *Am J Public Health*, 91, 400-405.

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³Rotheram-Borus, M.J. & Miller, S. (1998). Secondary prevention for youths living with HIV. *AIDS Care*, 10(1), pp.17-34.

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⁵Ewart C. (1991), Bandura A. (1994). Social action theory for a public health psychology. *Am Psychol.* 46(9), 931-946.

⁶Luna GC, Rotheram-Borus MJ. (1999). Youth living with HIV as peer leaders. *Am J Commun Psychol*, 27, 1-23.

⁷Rotheram-Borus MJ, Miller S. (1998). Secondary prevention for youths living with HIV. *AIDS Care*, 10(1), 17-34.

⁸Rotheram-Borus MJ, Luna GC, Marotta T, Kelly H. (1994). Going nowhere fast: Methamphetamine use and HIV infection: The context of HIV risk among drug users and their sexual partners. *Monographs of the National Institute on Drug Abuse*, 155-186.

⁹Luna GC. (1997). *Young people living with HIV: Self-evident truths*. New York, NY: Hayworth: Plenum Press.

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). *Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators*.

A complete copy of the TLC intervention is located at
<http://chipts.ucla.edu/interventions/manuals/>

CDC would like to acknowledge and thank the faculty and staff of the Center for HIV Identification, Prevention, and Treatment Services (CHIPTS) in the UCLA Center for Community Health for their assistance in compiling this Procedural Guidance for Implementation of Teens Linked to Care.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF HOLISTIC HARM REDUCTION PROGRAM

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF HOLISTIC HARM REDUCTION PROGRAM

The Holistic Harm Reduction Program (HHRP)¹ for HIV-positive injection drug users is a 12-session, manual-guided, group level program to reduce harm, promote health, and improve quality of life. Intervention materials including background information, and research, as well as manuals and instructional materials for individual and group sessions are available for download by clicking on the Training link at <http://www.3-S.us>.

The program is based on the Information, Motivation, Behavior (IMB) model of behavior change. The HHRP counselor manual was designed to be highly “user-friendly” as it contains both relevant background and theoretical material and detailed scripts for each session. This minimizes the need for extensive prior training. In this program, HIV-positive injection drug users are viewed as autonomous individuals responsible for making informed, personal choices concerning behaviors that pose varying degrees of risk to themselves and others. The primary goal of HHRP is to provide group members with the resources (i.e., knowledge, motivation, and skills) they need to make choices that reduce harm to themselves and others.

Because HIV-positive injection drug users may have unique medical and psychological problems that contribute to illicit drug use and other high-risk behavior, and which may include neuropsychological and/or psychiatric impairment, addressing these problems may help clients to make healthier lifestyle choices for health promotion. Therefore, in addition to providing substance abuse treatment, HHRP addresses medical, emotional, and social problems that may impede harm reduction behaviors, and uses cognitive-remediation strategies to improve knowledge, increase motivation, and teach skills needed for harm reduction and health promotion. In this setting abstinence from illicit drugs or sexual risk behaviors is seen as one of several treatment goals. These goals could also include reduced drug use, reduced risk of HIV transmission, and improved medical, psychological, and social functioning.

Finally, HHRP activities are designed to address clients as complex human beings in search of physical, emotional, social, and spiritual well-being. By including strategies such as relaxation training and respect for clients’ spiritual and religious beliefs, the program aims to assist clients in achieving serenity in the expression of their lives. This can lead to a reduction in behaviors that cause harm to self and others.

When compared to an Enhanced Methadone Maintenance Program (EMMP) which includes a 6-session HIV risk reduction component, participants in both the EMMP and HHRP groups

exhibited significant improvements on measures of addiction severity, harm reduction behaviors, harm reduction knowledge, motivation, behavioral skills, and quality of life. Members of the HHRP group had significantly greater improvement in behavioral skills and showed continued decreases in addiction severity and risk behavior after 3 months. Members of the control group did not maintain gains.

Intervention materials including background information, and research, as well as manuals and instructional materials for individual and group sessions are available for download by clicking on the Training link at <http://www.3-s.us/>.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. The Holistic Harm Reduction Program has 6 core elements which include:

- 1) HHRP is a 12-session, manual-guided group intervention for HIV-positive injection drug users with three primary treatment goals – harm reduction, health promotion, and improved quality of life.
- 2) HHRP's focus on harm reduction entails reducing drug use and other high-risk behaviors, including sharing of drug paraphernalia and unsafe sexual practices. Although abstinence from illicit drug use is a primary aim of treatment, patients who do not attain abstinence, but who reduce drug use and other harmful behaviors, are not considered treatment failures.
- 3) HHRP's focus on health promotion entails addressing medical, emotional, and social problems that may be associated with disease progression, and includes enhancing medication adherence, improving communication skills with health care providers, and becoming informed concerning basic health components.
- 4) HHRP's focus on improving quality of life entails respecting and drawing upon clients' spiritual and religious beliefs, helping clients cope with stigma and grief, teaching stress management techniques, and acknowledging and addressing fears of death and dying.
- 5) HHRP is guided by the IMB model. Each group provides patients with the information, motivation, and behavioral skills needed to attain and implement treatment goals in real world settings.
- 6) Because HIV-positive injection drug users may present to treatment with mild to moderate cognitive difficulties, HHRP utilizes easily administered, cognitive remediation strategies, such as behavioral games and visual presentation of material (e.g., slides). Behavioral games and visual presentation materials are included in the treatment manual

to help improve knowledge, increase motivation, and teach skills needed for harm reduction, health promotion, and improved quality of life.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. HHRP has 5 key characteristics:

- Group sessions are held at the same time and place each week and follow the same structured format.
- Groups include between 3 and 15 participants.
- Groups are co-facilitated by two substance abuse counselors with experience working with HIV-positive substance abusers and who are comfortable with the concepts of harm reduction in this population.
- The facilitation team should include one male counselor and one female counselor, if possible.
- At least one of the counselors co-facilitating the interventions should have a master's degree in a counseling discipline.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for HHRP follow.

Sessions: The HHRP manual provides 12, two-hour group sessions that can be presented as 1 weekly two-hour session for 12 weeks (recommended); or 2 weekly one-hour sessions for 12 weeks, or 1 two-hour session alternating with discussion groups weekly for 24 weeks. The manual provides an individual treatment orientation session that can be provided prior to the client beginning group treatment.

Content: The 12 session topics include:

- Session 1: Setting and reaching goals
- Session 2: Reducing the harm of injection drug use
- Session 3: Harm reduction with latex
- Session 4: Negotiating harm reduction with partners
- Session 5: Preventing relapse to risky behavior
- Session 6: Health care participation
- Session 7: Healthy lifestyle choices
- Session 8: Introduction to the 12-step program
- Session 9: Overcoming stigma
- Session 10: Motivation for change: overcoming helplessness
- Session 11: Moving beyond grief
- Session 12: Healthy social relationships

Format: To address the psychiatric and neuropsychological needs that are often present in clients who are dealing with substance abuse issues, the sessions of HHRP are presented using

multiple teaching approaches so all persons can learn, regardless of learning style. These strategies include:

- 1) Multimodal presentation of materials including verbal (lectures and discussion), visual (slides, videos, charts, and written material), and skills-building (games, practice, role-plays) modalities.
- 2) Frequent reviews to facilitate learning and retention.
- 3) Reduction of the fatigue and distraction which impede learning and may be particularly problematic for cognitively impaired clients. Frequent breaks, multimodal presentations, and minimizing outside noise/distractions help to improve concentration and achieve this goal.
- 4) Provide consistency by meeting at the same time and place each week, providing an agenda, and following the same structured format.
- 5) Assessment and feedback regarding knowledge and skills gained. This allows members to evaluate the different learning and teaching strategies and also provides a chance for additional practice of new skills.
- 6) Generalizability of information presented to the life situations of group members.
- 7) Memory book system to improve memory for session material and for organizing and remembering activities required for living a healthy lifestyle.
- 8) Learning by doing through activities that are appropriate to the group topic and aid in skills acquisition, retention, and self-confidence. Immediate feedback during games can reinforce appropriate behaviors, discourage less helpful behaviors, and increase self-esteem and self-confidence.
- 9) Management of stress through visualization strategies focused on relaxation and health promotion. Stress can impair concentration, increase cognitive dysfunction (such as memory difficulties or impulsivity), and potentially lead to relapse.
- 10) Group treatment modality to permit generalizable pro-social behaviors to be practiced and strengthened. This can reduce feelings of isolation and provide a sense of interpersonal support from individuals with similar life circumstances.

Counselors: HHRP groups are optimally co-facilitated by two substance abuse counselors with experience working with HIV-positive substance abusers and are comfortable with the concept of harm reduction in this population. A male/female team is recommended. The two counselors work as a team to facilitate all aspects of the groups, but one is primarily responsible for assuring that all material is presented in accordance with the manual, while the second is primarily responsible for experiential aspects of the group. Counselors must establish group structure, provide a consistent model of behavior and behavior change, and employ a consistent non-

judgmental therapeutic style to assist the client in reaching his/her own harm reduction goals. The HHRP manual furnishes counselors with all the materials they will need to provide the intervention with a minimal amount of training necessary (i.e., detailed scripts are available for each group session and all necessary visual aids [slides or PowerPoint format], learning activities, and quizzes. HHRP counselors should receive on-going supervision from a clinically trained professional with experience in harm reduction.

Mechanism of Behavior Change: The HHRP takes a harm-reduction approach to behavior change in which abstinence from drug use or sexual risk-taking behavior is one goal along a continuum of risk-reduction strategies. Clients are not assumed to be abstinent from either drug use or sexual risk behaviors. Risk behaviors are viewed as being sustained by hopelessness in the face of a life-threatening illness, high levels of stress, psychiatric disorders, and medical and social problems. In addition, the ability to acquire and retain the skills needed for change is impeded by HIV- and drug-related cognitive deficits. By presenting materials in such a way as to minimize the effects of cognitive difficulties, and providing clients with an empathic, directive, non-confrontational setting in which structure and consistency are emphasized, the HHRP intervention allows clients to meet their own harm-reduction goals.

RESOURCE REQUIREMENTS

To provide HHRP to up to 12 HIV-positive individuals, an agency will need two experienced counselors for each two-hour group session. We estimate that each counselor will need to receive between 12-24 hours of training in HHRP prior to conducting the intervention. An agency will also need audio-visual equipment, such as a slide projector and screen (or PowerPoint projector and screen), a TV/VCR with remote control, and easel, easel chart paper, and markers. Funds will also be needed for small prizes (valued at \$5-10) that are awarded at each group session.

RECRUITMENT

The original HHRP intervention was offered to clients in a methadone maintenance clinic. The intervention can be adapted to reach clients in any drug treatment program, or in a community-based organization (CBO) serving a high percentage of PLWH with substance abuse and dependence issues. Agencies wishing to implement HHRP should review the Procedural Guidance for Recruitment (see p. 11) in order to choose a recruitment strategy that will work in the setting in which they plan to implement HHRP.

PHYSICAL SETTING CHARACTERISTICS

This intervention is most appropriate for a facility that treats clients with substance abuse/dependence issues. It can be implemented in a methadone maintenance or other drug treatment facility or in a CBO serving a high percentage of drug using, HIV-positive clients. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room, or outside noise levels.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement HHRP the following policies and procedures should be in place to protect participants, the agency, and the HHRP program team:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that by virtue of participation in HHRP, clients will be disclosing their HIV status. With that in mind, agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants, as necessary. Providers must know about referral sources for prevention interventions/counseling (Prevention Case Management, Partner Counseling and Referral Services, Health Department/Community-based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both facilitators and participants should be in place when implementing HHRP:

Facilitator: The HHRP manual is comprehensive and contains detailed scripts for each session. Additional training required for facilitators will depend upon the facilitator's level of expertise, but could include the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practice with mock intervention sessions. Agencies should have in place a mechanism to ensure that all session protocols are followed as written. Quality assurance activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on adherence to session content, use of multimodal presentation of material; use of role-play; use of behavioral games as teaching aids, and comfort with the non-judgmental, non-confrontational approach to treatment. Weekly supervision should ensure that treatment is provided in accordance with the HHRP manual, that ways to adapt the manual are discussed, and that process counselor concerns are shared. Selected intervention record reviews should focus on assuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at each session.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.

- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **III.A-** Proportion of persons living with HIV, their sex partners and injection drug-using contacts who are HIV negative or who do not know their HIV status who completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
 - **III.C-** Percent of HIV infected persons who, after a specified period of participation in each of the prevention interventions supported by the program announcement, report a reduction in sexual or drug-using risk behaviors or maintain protective behaviors with seronegative partners or with partners of unknown status.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.

KEY ARTICLES AND RESOURCES

¹Margolin A, Avants SK, Warburton LA, Hawkins KA, Shi J. (2003). A randomized clinical trial of a manual-guided risk reduction intervention for HIV-positive injection drug users. *Health Psychology*, 22(2) 223-228.

²Copenhaver M, Avants SK, Margolin A, Warburton LA. (2003). Intervening effectively with drug abusers infected with HIV: Taking into account the potential for cognitive impairment. *Journal of Psychoactive Drugs*, 35(2), 209-218.

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). *Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators*.

Intervention materials including background information, and research, as well as manuals and instructional materials for individual and group sessions are available for download by clicking on the Training link at <http://www.3-s.us/>.

CDC would like to acknowledge and thank the faculty and staff of the Harm Reduction Unit, Division of Substance Abuse, Department of Psychiatry, Yale University School of Medicine for their assistance in compiling this Procedural Guidance for Implementation of the Holistic Harm Reduction Program.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF HEALTHY RELATIONSHIPS

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF HEALTHY RELATIONSHIPS

Healthy Relationships¹ is a 5-session, small-group intervention for men and women living with HIV/AIDS. It is based on Social Cognitive Theory and focuses on developing skills and building self-efficacy and positive expectations about new behaviors through modeling behaviors and practicing new skills. An intervention package, training, and technical assistance on the Healthy Relationships intervention will be available from CDC in July 2004.

The intervention addresses building skills to reduce stress in three life areas: disclosure of HIV status to family and friends, disclosure to sex or needle sharing partners, and adoption of safer sexual behaviors. Decision-making and problem-solving skills are developed to enable the participants to make informed and safe decisions about disclosure and behaviors. In each of the three life areas, a series of exercises is repeated to create and develop decision-making and problem-solving skills. The primary exercise is role-playing based on scenarios that are established by viewing short clips from popular movies. The intervention is adaptable to different populations by varying the choice of movie clips and providing flexibility in implementing role plays to allow for cultural influences. Healthy Relationships is intended to create a positive, engaging, and creative atmosphere that can be integrated into existing support groups or can be introduced as a new program.

Compared to a health maintenance control group, participants in the Healthy Relationships intervention group reported greater self-efficacy for suggesting condom use with new sex partners and being able to satisfy sex partners and themselves even when practicing safer sex. Participants also reported intentions to consider the pros and cons of HIV status disclosure to partners and to engage in safer sex with partners who did not know their HIV status. At 3-month and 6-month follow-up contacts, intervention group participants were significantly more likely than the control group to have followed through on their earlier intentions and to have considered the pros and cons of HIV status disclosure to sex partners. At the 6-month follow-up the intervention group participants were significantly more likely to have refused to engage in unsafe sex (which was not true at the 3-month follow-up). The intervention group participants also reported less unprotected intercourse, more protected intercourse, and fewer sexual contacts than the control participants at the 6-month follow-up. Furthermore, they had less sexual intercourse and less unprotected intercourse with non-HIV-positive partners at both the 3- and 6-month follow-ups. These results demonstrate that this intervention is broadly applicable across subpopulations, including persons of different sexual orientations, with a history of incarceration,

current or past drug use, or psychiatric history, and indicates a long-term effect (at least up to 6-months) on both reported behaviors and perceived self-efficacy.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Healthy Relationships has 5 core elements which include:

- 1) Defining stress and reinforcing coping skills with HIV-positive people across three life areas:
 - a. disclosing to family and friends,
 - b. disclosing to sexual partners,
 - c. building healthier and safer relationships.
- 2) Using modeling, role-play, and feedback to teach and practice skills related to coping with stress.
- 3) Teaching decision-making skills around the issue of disclosure of HIV status.
- 4) Providing participants with personal feedback reports to motivate change of risky behaviors and continuance of protective behaviors.
- 5) Using popular movie clips to set up scenarios around disclosure and risk reduction to stimulate discussions and role-plays.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Healthy Relationships has 9 key characteristics:

- Participants meet in small groups, similar in style to support groups. New members cannot join once the series of sessions has begun.
- Participants sit in a circle, face-to-face.
- Participants meet for at least five, 120-minute sessions.
- Groups contain members of the same gender and sexual orientation.
- At least one group facilitator is an experienced and skilled counselor, preferably a mental health professional. This facilitator may or may not be HIV-positive.
- The peer facilitator should be HIV-positive.*
- One facilitator is male and the other female.*
- At least one facilitator matches the ethnicity of the majority of the participants.*

- Both facilitators need the personal characteristics and group skills of effective facilitators.

* These particular key characteristics bring immediate credibility and rapport with group participants.-

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for Healthy Relationships follow.

Healthy Relationships is based on interactive sessions that educate and engage participants. They are not classes, lectures, or forums. These sessions create a context where people can interact, examine their risks, develop skills to reduce their risks, and receive feedback from others.

Groups consist of 5 to 12 people of similar backgrounds. Participants sit in a circle so that they can easily see each other, share experiences, practice new skills, and receive feedback from their peers. Two facilitators, one of whom is an HIV-positive peer, use easel chart guides to lead participants through the Healthy Relationships content.

Each participant completes an initial assessment survey. From this survey three personal feedback report (PFR) forms are created for each participant from their initial assessment survey interview. These PFR forms are designed to reinforce participants' motivation to change by helping them identify their behaviors, as well as which behaviors they want to change and which they want to maintain. The PFR forms are distributed in three different sessions, each one tied to one of the life areas mentioned in core element number one.

Three risk continuum exercises occur after each PFR is distributed and discussed. The continuum exercises use a long banner with a double-ended arrow labeled from high to low. The line of the arrow and the cards have corresponding pieces of Velcro fasteners on their backs to allow them to be attached and detached easily from the banner.

The continuum banner is used in three of the sessions, each time with a different set of cards. These exercises focus on how the participants view each of the following:

- Exercise 1: risk/stress of disclosure to family and friends
- Exercise 2: risk/stress of disclosure to sexual partners
- Exercise 3: risk of various sexual behaviors

Participants attach the cards given to them based on their personal evaluation of the stress or risk involved.

There are a variety of videos and movie "clips" shown in the five sessions of Healthy Relationships: personal statements, HIV/AIDS information, condom demonstration, and, most importantly, segments from popular movies. The term clip is used, regardless of whether the clip is short or long or even an entire video. Facilitators give brief descriptions or scenarios to introduce clips while tying them to the objectives of that session. Correctly setting up the scenarios facilitates both role-playing and discussion. These scenario descriptions are also used on many of the easel chart guides.

RESOURCE REQUIREMENTS

To conduct Healthy Relationships, an agency will need a 100% full-time equivalent (FTE) paid, experienced counselor, one 25% FTE peer facilitator (volunteer or paid) for each population of people living with HIV (PLWH) (e.g., women, heterosexual men, MSM) for whom Healthy Relationship sessions will be offered, and one 25% FTE program manager for evaluation and quality assurance. We estimate that each counselor and peer facilitator will need to attend at least 24 hours of training in Healthy Relationships. An agency will need from 40 to 60 hours to find and assemble 13 video/movie clips to use during the sessions (4 video clips will be provided in the intervention package). The actual number of hours and costs for assembling the clips depends on 1) staff knowledge of movies and appropriate clips, 2) equipment access and staff skill to assemble clips on a VCR tape or DVD disk or contract for these services, and 3) the number of populations of PLWH who will be receiving the intervention (most of the selections are population-specific). An agency will need to acquire, if they do not already own, a TV/VCR with remote control or a DVD player with remote control. The intervention also involves the use of an easel, easel chart paper, and markers. Small incentives may be used to encourage participation, and one small prize may be given away through a random drawing at the end of each session.

RECRUITMENT

The following recruitment strategies can be used to reach PLWH:

- Recruit from support groups.
- The Healthy Relationships package comes with generic marketing tools including a video and printed promotional literature that can be modified for specific populations.
- Send press releases to local radio and TV stations.
- Advertise in local newspapers, including gay and alternative papers.
- Post announcements on the Internet.

Agencies wishing to implement Healthy Relationships should review the Procedural Guidance for Recruitment in this document in order to choose a recruitment strategy that will work in the setting in which they plan to implement Healthy Relationships.

PHYSICAL SETTING CHARACTERISTICS

In order to select sites to perform Healthy Relationships, agencies should first consider the sites' capacity to provide audio and visual equipment, specifically a TV and VCR or DVD player with a remote control. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room or outside noise levels. Not all of the intervention participants will have disclosed their HIV status and may not feel comfortable with others knowing; therefore, the intervention site should be at a discrete location.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement Healthy Relationships, the following policies and procedures should be in place to protect participants, the agency, and the Healthy Relationships intervention team:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that by virtue of participation in Healthy Relationships, clients will be disclosing their HIV status. With that in mind, agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants, as necessary. Providers must know about referral sources for prevention interventions/counseling (Prevention Case Management, Partner Counseling and Referral Services, Health Department/Community-based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both facilitators and participants should be in place when implementing Healthy Relationships:

Facilitator: Training for facilitators should address the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practicing mock intervention sessions. Agencies should have in place a mechanism to ensure that all session protocols are followed as written. Quality assurance activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on adherence to session content, use of appropriate videotapes with adequate facilitation of discussions, accessibility and responsiveness to expressed participant needs, and important process elements (e.g., time allocation, clarity). Selected intervention record reviews should focus on ensuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at each session.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:

- **III.A-** Proportion of persons living with HIV, their sex partners and injection drug-using contacts who are HIV negative or who do not know their HIV status who completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
- **III.C-** Percent of HIV infected persons who, after a specified period of participation in each of the prevention interventions supported by the program announcement, report a reduction in sexual or drug-using risk behaviors or maintain protective behaviors with seronegative partners or with partners of unknown status.
- **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information

KEY ARTICLES AND RESOURCES

¹Kalichman SC, Rompa D, Cage M, DiFonzo K, Simpson D, Austin J, Luke W, Buckles J, Kyomugisha F, Benotsch E, Pinkerton S, & Graham. Effectiveness of an intervention to reduce HIV transmission risks in HIV-positive people. *American Journal of Preventive Medicine* 2001;21(2):84-92.

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). *Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators*.

An intervention package, training, and technical assistance on the Healthy Relationships intervention will be available from CDC starting in July 2004.

CDC would like to acknowledge and thank the faculty and staff of the Dallas STD/HIV Prevention Training Center for their assistance in compiling this Procedural Guidance for Implementation of Healthy Relationships.

SECTION 3, Part B: Prevention for Individuals at Very High Risk for HIV Infection

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF PREVENTION CASE MANAGEMENT (PCM) FOR UNINFECTED PERSONS AT VERY HIGH RISK FOR HIV

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF PCM FOR UNINFECTED PERSONS AT VERY HIGH RISK FOR HIV

Prevention Case Management (PCM) is a client-centered HIV prevention activity with the fundamental goal of promoting the adoption and maintenance of HIV risk-reduction behaviors by clients with multiple, complex problems and risk-reduction needs.^{1,2} PCM provides client-centered, multiple-session HIV risk-reduction counseling to help individuals initiate and maintain behavior change to prevent the acquisition of HIV while addressing competing needs which may make HIV prevention a lower priority. This HIV prevention activity addresses the relationship between HIV risk and other issues such as substance abuse, mental health, social and cultural factors, and physical health.

As a hybrid of HIV risk-reduction counseling and traditional case management for PLWH, PCM provides intensive, on-going, individualized prevention counseling, support, and service brokerage. Priority for PCM services should be given to persons at very high risk for HIV defined as someone who, within the past 6 months, has had unprotected sex with a person who is living with HIV, unprotected sex in exchange for money or sex, multiple (greater than 5) or anonymous unprotected sex or needle-sharing partners, or been diagnosed with a sexually transmitted disease. PCM services might include traditional risk reduction topics such as abstinence, decreasing the number of sexual/needle-sharing partners or increasing condom use, as well as other subjects including referral to needed medical and psychosocial services affecting risk behavior, such as mental health and substance abuse treatment services or diagnosis and treatment of sexually transmitted diseases.

CORE ELEMENTS, KEY CHARACTERISTICS AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. PCM has 6 core elements which include:

- 1) PCM is a hybrid of HIV risk reduction counseling and traditional case management.
- 2) PCM is based on the premise that some people may not be able to prioritize HIV prevention when they face problems perceived to be more important and immediate.
- 3) HIV-negative persons, or those of unknown serostatus are eligible when they have a recent history (past 6 months) of unprotected sex with a person who is living with HIV, unprotected sex in exchange for money or sex, multiple (greater than 5) or anonymous unprotected sex or needle-sharing partners, or been diagnosed with a sexually transmitted disease.
- 4) Individuals who are committed to participating in ongoing risk reduction counseling should be targeted.
- 5) Organizations must hire case managers with the appropriate training and skills to complete the PCM activities within their job description.
- 6) Clear procedure and protocol manuals for the PCM program must be developed to ensure effective delivery of PCM services and minimum standards of care.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. PCM has 8 key characteristics:

- Develop a client recruitment and engagement strategy.
- Screen and assessing clients to identify those who are at highest risk and are appropriate for PCM.
- Develop a written, client-centered prevention plan.
- Provide multiple HIV risk-reduction counseling sessions.
- Provide active coordination of services with follow-up.
- Monitor and reassess clients' needs, risks, and progress.
- Establish protocols to classify clients as "active," "inactive," or "discharged," and outlining the minimum active effort required to retain clients.
- Discharge clients from PCM upon attainment and maintenance of risk reduction goals.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the conduct of the intervention. Procedures for PCM follow:

Upon the client's introduction to the PCM program, providers should assure that clients understand the reason for the referral, the role of the PCM program, and the role of the provider. Written, informed consent describing all relevant policies and procedures (including the confidential and voluntary nature of the service) and a commitment to participate in ongoing risk-reduction counseling should be obtained. Clients should be provided a copy of this consent, and the original should be maintained in an individual client record. Each client should have an

individual confidential file, and all records should be kept in a locked file cabinet with access limited to the prevention case manager and his/her immediate supervisor.

All clients must be screened for eligibility for services. Appropriate screening procedures should be developed to identify persons at highest risk for transmission or acquisition of HIV. Assessment should address HIV and STD transmission risks, substance use/abuse, and medical and psychosocial needs, and care should be taken to assure that the assessment is conducted in a culturally appropriate manner.

After completion of the assessment, the PCM provider and the client should collaborate on the development of a prevention plan which is then signed by the client and provider. The plan should outline and define risk-reduction behavioral objectives and strategies for behavioral change. In addition to risk reduction goals, the plan should include referral to appropriate medical care if needed. The plan must also include referral for evaluation and treatment of STDs, TB, hepatitis and other related health concerns at regular intervals, and should address referral for substance abuse treatment if necessary. Prevention plans for HIV-negative or unknown serostatus clients should include goals related to counseling and testing as necessary. Finally, plans for referral follow-up should be outlined.

When risk behaviors have been identified and appropriate risk-reduction strategies have been outlined, prevention case management sessions begin. Multiple counseling sessions are aimed at meeting the identified behavioral objectives. These sessions may include education, skill development, role-play, support, or other techniques. Client notes should be filed after each session indicating, at a minimum, the goal addressed during the session, progress toward the goal, barriers to implementation of behavior change and the way these are or will be addressed, referrals made with plans for follow-up, and a plan for the next session.

PCM providers should assure active coordination of services with follow-up to avoid duplication of services (for example, agency protocols should address co-managing clients with other case managers if appropriate). If referrals are to be made as a part of the prevention plan, the agency should have a standardized written referral process, and a system should be in place to ensure availability and access to these referrals and to track their completion. This system might include formal or informal agreements including memoranda of agreement with relevant service providers. Written informed consent from the client for sharing client information should be obtained before communication between agencies begins. Medical and psychological services should be available if emergencies arise, and referral agreements for these services should be in place before initiating PCM. Current referral and access information for all community providers should be maintained.

Ongoing needs assessment is essential to monitor progress toward PCM goals and to monitor changing needs of the client. Prevention plans must be updated to reflect any change. Upon attainment and maintenance of the objectives of the plan a determination should be made by the client and the PCM provider that the client is ready for discharge from PCM. Agencies implementing PCM must have discharge protocols in place to ensure that discharged clients are connected to needed services and resources, and a return to PCM is available if needed.

RESOURCE REQUIREMENTS

Because prevention case management is an intervention with a great deal of overlap with mental health services, providers must have experience in managing mental health issues (a licensed counseling or mental health provider is preferred). Staffing levels will vary according to the number of clients that an agency expects to serve and the availability of other services in the area in the service area. In areas with limited referral sources, the PCM provider will be expected to meet multiple needs for his/her clients thus reducing case load for individual providers. In resource-rich areas, more service needs can be met by referral and a PCM provider can therefore be expected to carry a larger caseload. Programs should consider the number of clients to be served, the needs of those clients and the services available in their area when determining staffing levels needed, but a typical caseload will include approximately 15 - 20 clients for each 1.0 FTE PCM provider.

RECRUITMENT

PCM programs rely upon referrals and recruitment to establish a client base. To enlist clients for PCM, programs should be located in a setting with other services for the targeted population. In this way, clients can be referred from existing services that the program offers including outreach, counseling and testing services, medical care, STD assessment and treatment, substance abuse treatment, or mental health services. If these services are not offered on site, referral agreements from agencies providing these services should be established. Incentives (for example, bus tokens, hygiene kits, t-shirts) can be used to increase participation.

Agencies wishing to implement PCM should review the Procedural Guidance for Recruitment in order to choose a recruitment strategy that will work in the setting in which they plan to implement PCM.

PHYSICAL SETTING CHARACTERISTICS

Agencies implementing PCM should choose a location that is easily accessible from public transportation routes. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room, or outside noise levels. It may be necessary for providers to meet clients outside of an office setting. In this case, efforts should be made to secure a location that will assure the confidentiality of the client and minimize distractions and interruptions. Regardless of where actual PCM sessions occur, the agency implementing the intervention must assure that all records are maintained in a locked file cabinet or in a secured computer workstation.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement PCM the following policies and procedures should be in place to protect participants, the agency, and the Prevention Case Manager:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in accessible language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility if a PCM client tests positive for HIV. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, or other Health Department/Community Based Organization prevention programs) if consumers need additional assistance in decreasing risk behavior. All persons screened for PCM, regardless of eligibility, should be offered counseling by a prevention case manager and referrals relevant to their needs.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both providers and participants should be in place when implementing PCM:

Provider: Providers of PCM services should have experience working in the fields of mental health services and HIV prevention (a licensed counseling or mental health provider is preferred). Agencies should have in place a mechanism to assure that all sessions address the prevention plan. QA activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on the quality of and appropriate adherence to the prevention plan, accessibility and responsiveness to expressed client needs; and important process elements (e.g., time allocation, clarity). PCM providers should meet at least monthly with either a direct supervisor or with a peer supervisor. Selected intervention record reviews should focus on assuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to assure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at regular intervals of the agency's choosing.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).

- **III.B-** Proportion of persons at very high risk for HIV infection that completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
- **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information

KEY ARTICLES AND RESOURCES

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UCSF, AIDS Policy Research Center, Prevention with Positives Resources

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF VOICES/VOCES

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF VOICES/VOCES

Video Opportunities for Innovative Condom Education and Safer Sex (VOICES/VOCES) is a single-session, video-based HIV/STD prevention workshop designed to encourage condom use and improve condom negotiation skills among African-American and Latino men and women.¹ The original research was conducted in STD clinics; however, the intervention has also been used in family planning centers, community health centers, drug rehabilitation clinics, correctional facilities and other settings. VOICES/VOCES is a brief bilingual English and Spanish) HIV prevention intervention that is designed to be easily integrated into the flow of services provided by busy community-based agencies. It fits effective prevention education into the time frame of a clinic visit or other brief opportunity to reach clients during a “teachable moment.” VOICES/VOCES targets people who are at very high risk for HIV/STDs. This intervention has been packaged by CDC’s Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

To implement the VOICES/VOCES intervention, health educators convene groups of four to eight clients in a room that allows privacy for discussion. Whenever possible, groups are gender- and ethnic-specific, so that participants can develop prevention strategies appropriate for their culture. Information on HIV risk behaviors and condom use is delivered using videos, facilitated group discussion, and a board presenting features of various condom brands in English and Spanish. Two culturally-specific videos are used: one for African-American participants and a bilingual video for Latinos. Skills in condom use and negotiation are modeled in the videos, then role-played and practiced by participants during the discussion that follows. At the end of the single, 45-minute session, participants are given samples of the types of condoms they have identified as best meeting their needs.

VOICES/VOCES is one-time 45 minute intervention that produced significant results in field trials, demonstrating both biological markers and self-reported behavior change. Participants in VOICES/VOCES had a significantly lower rate of new STD infection than participants in the comparison condition. In addition, participants had increased knowledge of the transmission of HIV and other STDs as well as intentions to use condoms regularly. They were also more likely to go get more condoms at a neighborhood store in the weeks after their clinic visit.¹

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. of VOICES/VOCES has 4 core elements:

- 1) Viewing culturally-specific videos portraying condom negotiation.
- 2) Convening small group skill-building sessions to work on overcoming barriers to condom use.
- 3) Educating program participants about different types of condoms and their features.
- 4) Distributing samples of condoms identified by participants as best meeting their needs.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. Key characteristics of VOCES/VOCES are:

- Introducing VOICES/VOCES as a routine part of clinic/agency services
- Convening 4 to 8 persons of the same gender and race/ethnicity to allow for open discussion of sensitive issues among persons holding similar cultural values
- Conducting the intervention session in a private space
- Delivering the intervention in a single 40- to 60-minute session
- Viewing a 15- to 20-minute culturally-specific video as the intervention's starting point
- Showing a brief video that:
 - reflects up-to-date information on HIV/STDs
 - uses male and female actors with racial and ethnic backgrounds similar to the persons viewing the video
 - depicts real-life situations involving characters like the clients themselves
 - shows condom negotiation as a shared responsibility between sex partners
 - models communication skills & HIV/STD prevention attitudes and behaviors
 - includes subject matter that is explicit, but appropriate for viewing at your site
- Using the characters and situations depicted in the video to launch group discussion
- Addressing barriers to condom use and safer sex by
 - increasing awareness of personal risk for HIV/STD infection
 - providing information on safer sex to prevent infection
 - correcting misinformation about condom use
 - presenting the features of different types of condoms to address objections to using condoms

- having clients practice correct condom use and condom negotiation to enhance their self-efficacy
- Providing three condoms to each client of the type they identified as best meeting their needs

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the conduct of the intervention. Procedures for implementing VOICES/VOCES follow:

Viewing of Culturally Specific Video

Videos quickly transmit necessary information and model attitudes and behaviors regarding safer sex appropriate to members of particular cultures. In VOICES/VOCES, videos provide a non-threatening starting point for groups of strangers, brought together for one brief session, to discuss intimate topics and behaviors. Videos also provide a safe context for discussing culturally-sensitive issues. This context is especially important when the race/ethnicity or other characteristics of group facilitators are not the same as group participants—as is often the case with community health agencies providing services to diverse client populations.

Two videos have been developed for the VOICES/VOCES intervention: *Porque Sí* and *Love Exchange*. Each is tailored to the needs of its particular target population. *Porque Sí*, a bilingual Spanish and English video, is designed to be used with Latino men and women. *Love Exchange* is directed toward African-Americans.

Other videos may be substituted or included in the intervention as long as they meet the criteria outlined in the VOICES/VOCES Implementation Manual.

Small-Group Skill-Building Sessions

The interactive sessions that follow video viewing are the heart of the VOICES/VOCES intervention. These sessions help clients develop and practice the skills they need to negotiate condom use. They provide an opportunity for participants to discuss problems they have encountered in trying to adopt safer sex behaviors, and, with peers, develop and practice strategies for overcoming these problems. Facilitators lead groups made up of four to eight clients, using a standardized protocol to guide discussion. Facilitators begin by asking participants specific questions about the characters and events depicted in the video. Facilitators then encourage participants to relate these situations to their own lives. Sessions address barriers to condom use and safer sex by providing information, correcting misinformation, discussing condom options, and having clients practice condom-negotiation techniques. Sessions follow a consistent format, but the content is tailored to address the concerns and experiences of each group of participants. If possible, groups should include members of the same gender; that is, they should be men only or women only, to allow for open discussion of sensitive issues surrounding sexual behaviors and attitudes.

Condom Feature Education

The condom education component of the intervention supplements the skill-building session by providing clients with detailed information about condoms and how to choose a condom that they and their partner will feel most comfortable using. This component offers aids to familiarize clients with condoms and their features, making it easier for them to obtain and correctly use condoms. The bilingual Condom Features Poster Board, available in the intervention kit, is used for this activity.

Distribution of Sample Condoms

At the end of the VOICES/VOCES session, participants are given samples of the types of condoms they have identified as best meeting their needs.

RESOURCE REQUIREMENTS

In most situations, current agency staff can easily learn to implement VOICES/VOCES. Key to the success of VOICES/VOCES is 1-2 staff who facilitate or implement the intervention and an agency manager who will oversee and support implementation. Staff facilitators should have the skills to identify and recruit clients to participate in a small-group intervention, to show the video, and to conduct the small-group skill-building sessions. Current staff members may be qualified to undertake this new responsibility. Having more than one staff facilitator helps assure that continuity of the program and consistency in the case of absences or turnover. Facilitators also can provide one another support and help trouble shoot any issues that arise.

Also critical to the adoption and success of the intervention is the manager who is willing to act as an intervention “champion.” In this role, the manager oversees maintenance, quality control, and documentation. The manager introduces the intervention, supports it through implementation, and sees that it becomes a regular part of services. The manager can also help secure resources, work in partnership with local and state public health agencies, identify and address potential problems, answer questions, and, in general, serve as an advocate for improved prevention services.

There are recommendations for staff preparation for adopting and implementing VOICES/VOCES. Managers who provide guidance and leadership on the VOICES/VOCES intervention must attend a half-day orientation to the intervention, its objectives, and resource needs. Staff facilitators who will be convening and conducting group sessions also attend this half-day training with managers as well as a one and a half day training on how to conduct the intervention, practice group facilitation skills, and identify agency-specific implementation strategies.

To implement VOICES/VOCES start-up costs can include purchase of video equipment as well as the costs of staff training and orientation. Some of the costs associated with intervention maintenance can include such categories as ongoing personnel costs for running the VOICES/VOCES group sessions (including both facilitator and supervisor time), the rental/space costs of the room required for holding groups, materials (such as condoms) replacement, and ongoing technical assistance. Because VOICES/VOCES is primarily intended to be fit into the opportunity provided by a client's routine visit to an STD clinic or similar health

service or community agency, additional costs incurred by participants are often negligible, since little additional travel or time investment is required.²

RECRUITMENT

Implementing VOICES/VOCES involves recruiting clients from your agency to participate in same-gender, same-ethnic small groups. Make VOICES/VOCES a part of routine services, and offer it on a regular basis to as many clients who may benefit as possible every week. Successful recruitment involves determining where VOICES/VOCES fits into the flow of your agency services. Agency staff can recruit clients who are at very high risk for HIV and other STDs and enroll them into group sessions presenting the intervention as part of the client's regular clinic visit. General recruitment into the VOICES/VOCES sessions can include word of mouth, and other marketing strategies including flyers, newsletters, and special events. Peer-to-peer recruitment strategies can also be effective ways to bring clients into the small groups

PHYSICAL SETTING CHARACTERISTICS

VOICES/VOCES was shown to be effective when delivered at a "teachable moment," for example, when a visit to an STD clinic may motivate a person to change behavior. However, many clients at very high risk for developing and transmitting HIV and other STDs are no longer treated in STD clinics, yet might benefit greatly from the VOICES/VOCES intervention. New users should examine their own clinic and agency settings and develop strategies for delivering the intervention so the greatest number of clients will benefit. Apart from STD clinics, recommended venues for implementation include family planning clinics, community health centers, community-based organizations, drug rehabilitation centers and correctional facilities. The main requirement of the physical setting include a private room, a television and a VCR.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement VOICES/VOCES, the following policies and procedures should be in place to protect participants, and the agency:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in accessible language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility if a client tests positive for HIV. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, or other Health Department/Community Based Organization prevention programs) if clients need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance for this intervention requires the agency manager/administrator to provide hands-on leadership and guidance for the intervention—from preparation through institutionalization. By attending the orientation session along with agency facilitators, the agency manager/administrator is prepared to provide this guidance.

The VOICES/VOCES implementation manual provides quality assurance and process monitoring and process evaluation procedures and describes the experience of others who have used the intervention. The implementation manual also guides staff on how to incorporate feedback and findings from quality assurance and process evaluations into VOICES/VOCES programming.

Throughout implementation, it is necessary to determine whether staff is delivering VOICES/VOCES with fidelity to the four core elements. It is also necessary to identify any issues that should be addressed to assure the intervention is meeting the needs of agency clients and staff. Staff implementing VOICES/VOCES will use the “Quality Assurance Checklist” contained in the Implementation Manual. This checklist helps staff to identify, discuss and solve problems in successfully implementing the intervention.

Staff will implement the Client Satisfaction Survey contained in the Implementation Manual or their own satisfaction survey to collect feedback from clients participating in the VOICES/VOCES intervention. Feedback will be used from the results of the survey to strengthen the implementation of the intervention.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC’s requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).
 - **III.B-** Proportion of persons at very high risk for HIV infection that completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information

KEY ARTICLES AND RESOURCES

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For more information on the VOICES/VOICES intervention, training and technical assistance or to get your name on a list for a future training, please go the website:
www.effectiveinterventions.org.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF THE SISTA PROJECT— A PEER LED PROGRAM TO PREVENT HIV INFECTION AMONG AFRICAN AMERICAN WOMEN

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF SISTA

The SISTA Project—or Sisters Informing Sisters About Topics on AIDS -- is a social skills training intervention aimed at reducing HIV sexual risk behavior among African American women at highest risk.¹⁻³ It is composed of five two-hour sessions delivered by peer facilitators in a community based setting. The sessions are gender – and culturally- relevant and include behavioral skills practice, group discussions, lectures, role play, a prevention video, and take home exercises. The five sessions that generate these discussions and activities include Ethnic/Gender Pride; HIV/AIDS Education; Self Assertiveness Skills Training; Behavioral Skills Management; and Coping. This intervention has been packaged by CDC’s Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

SISTA applies both the Social Cognitive Theory and the theory of gender and power. According to the Social Cognitive Theory, people need information (HIV risk-information), training in social and behavioral skills, and knowledge of norms to apply risk-reduction strategies. A change in behavior is dependent upon self-efficacy, self confidence, and outcome expectations.

The theory of gender and power is a social structural theory that accounts for gender-based power differences in male-female relationships. It examines, by gender, the division of labor and the distribution of power and authority within relationships and gender-based definitions of sexually appropriate conduct. In addition, the theory considers the impact of a woman’s willingness to adopt and maintain sexual risk-reduction strategies within heterosexual relationships as it pertains to her lack of power, her commitment to the relationship and her role in the relationship.

The study was originally implemented with 128 heterosexual women. Results indicated that a social skills training that is delivered in a community setting can positively affect condom use. Specifically, women in the experimental condition reported more condom use than women in the control condition.¹

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's or strategy's intent and design that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. SISTA has 7 core elements which include:

- 1) Small group sessions to discuss the session objectives, address the challenges and joys of being an African American woman, model skills development and role play women's skills acquisition.
- 2) Use of a skilled facilitator to implement the group sessions because the success of the SISTA Program depends on the skill of the facilitator.
- 3) Use of cultural and gender appropriate materials to acknowledge pride, enhance self worth in being an African American woman (e.g., use of poetry, artwork by African American women).
- 4) Training of women in sexual assertion skills so that they can both demonstrate care for partners and negotiate safe behaviors.
- 5) Teaching women proper condom use skills. SISTA is designed to foster positive attitudes and norms towards consistent condom use and provide women the appropriate instruction for placing condoms on their partner.
- 6) Discussions of the cultural and gender triggers that may make it challenging to negotiate safer sex.
- 7) Emphasis on the importance of the partner's involvement in safer sex. The homework activities that are included in the SISTA Project are designed to involve the male partner.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be adapted or tailored to meet the needs of the target population in different agencies and ensure cultural appropriateness of the strategy. SISTA has the following key characteristics:

- Flexibility to be tailored for different populations of African American women, for example, women in substance abuse treatment facilities, incarcerated women, women residing in shelters, and sex workers.
- Passion, such that the facilitators can deliver the intervention with conviction and purpose.
- Cultural competency, in that it was developed by African American women and for African American women.

- Broad content that includes discussions not only about HIV prevention, but also about relationships, dating, and sexual health.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for implementing the SISTA project follow.

The SISTA Project consists of:

- Five once-a-week sessions that are two hours each
- Two booster sessions administered two and four months after the project is completed, also two hours in length. These booster sessions are designed to provide an opportunity for the program participants to ask further questions and/or provide peer support
- A graduation party and a Certificate of Accomplishment for each of the participants after completion of the second booster session

Each of the sessions has a specific goal and objectives. The goals and activities of each of the sessions follow:

Session 1-Ethnic/Gender Pride:

Goal: Generate a discussion about being African-American and female, having pride in oneself, and valuing oneself.

During the first session, the facilitators will:

- Distribute an opening poem that will be read with and/or to the women
- Introduce themselves to the women, introduce the intervention to the women and introduce the women to each other
- Encourage the women to develop ground rules and expectations
- Facilitate a discussion about the positive qualities of black women and how they can be used as a source of strength and pride; conduct a discussion on values, requesting the women to prioritize their personal values
- Encourage the women to complete a simple homework exercise
- Distribute anonymous evaluation forms to assess the first session
- Read a closing poem with and/or to the women and recite the SISTA motto with the women

Session 2-HIV/AIDS Education:

Goal: Provide factual and statistical information on HIV/AIDS and other sexually transmitted diseases (STDs), correct misconceptions about HIV/AIDS, and discuss the importance of protecting oneself.

During session 2, the facilitators will:

- Distribute a copy of a poem that will be read with and/or to the women
- Review ground rules and expectations
- Review the key concepts of session 1 and discuss the homework exercise from day 1
- Distribute information and handouts on HIV/AIDS and initiate discussions about the information
- Engage the women in a Card Swap game to demonstrate how people get HIV and spread it to other people
- Present a 30 minute video and discuss
- Distribute homework assignments
- Distribute anonymous evaluation forms to assess the second session
- Recite the SISTA motto with the women.

Session 3-Assertiveness Skills Training:

Goal: Teach the distinction among assertive, aggressive and non-assertive behaviors and teach skills to initiate assertive qualities.

During the third session, the facilitator will:

- Distribute a copy of a poem that will be read with and/or to the women
- Review the key concepts of session 2 and discuss the homework exercise from day 2
- Facilitate a discussion on the difference between assertion and aggression
- Distribute a handout on various realistic situations and ask the women to provide examples and consequences of assertive, aggressive and non- assertive responses to the situations; discuss steps in the decision making process
- Distribute homework assignments will be distributed
- Distribute anonymous evaluation forms to assess the third session
- Read the closing poem with and/or to the women and recite the SISTA motto with the women

Session 4-Behavioral Self-Management:

Goal: Decrease participants' anxiety about condom use, demonstrate and role-play how to use condoms and discuss reasons that women do not insist upon using condoms.

During session 4, the facilitator will:

- Distribute a copy of a poem that will be read with and/or to the women
- Review the key concepts of session 3 and discuss the homework exercise from day 3
- Facilitate a discussion on why people do not use condoms and develop a strategy for overcoming these stated obstacles
- Distribute condom packets and lubricant
- Engage the women in a condom-card line-up activity to assess their knowledge of putting on a condom

- Demonstrate how to put on a condom
- Role play negotiation exercises
- Disseminate homework assignments
- Distribute anonymous evaluation forms
- Read the closing poem with and/or to the women and recite the SISTA motto with the women

Session 5-Coping Skills:

Goal: Initiate discussion about coping with life experiences -- including the link between alcohol and AIDS, coping with alcohol and sex, and coping with negative responses. This session also serves as a review of the previous sessions.

During the fifth session, the facilitator will:

- Distribute a copy of a poem that will be read with and/or to the women
- Review the key concepts of session 4 and discuss the homework exercise from day 4
- Review the handouts from previous sessions
- Discuss what coping is and its relationship to alcohol
- Distribute a handout on coping situations
- Inform the group of the booster sessions
- Distribute Anonymous Evaluation forms
- Read the closing poem with and/or to the women and recite the SISTA motto with the women

Booster Sessions: The booster sessions offer participants the opportunity to ask questions, stimulate thinking/knowledge of lessons learned, and reinforce the importance of protecting oneself. The first booster session is held two months after the last session of the intervention. The facilitator will facilitate discussions on (1) how the intervention could be strengthened; (2) whether the participants are using their newly developed skills; and, (3) any challenges that the participants have encountered. In addition, participants will begin designing their graduation ceremony.

The second booster session is held four months after the intervention. Additional questions are answered and the graduation ceremony is held.

RESOURCE REQUIREMENTS

The SISTA intervention should be facilitated by two peer health educators (at least one full time employee). Peers should be of the same race/ethnicity and gender as the target population. The staff should be well versed on HIV transmission and methods for preventing HIV transmission and should have a non-judgmental attitude toward people living with HIV/AIDS. Partnering agencies, if any, should be identified as well as a location to conduct a group session with 10-12 women.

Prior to implementing the intervention the staff should thoroughly review all program materials, plans, and logistics. Specific materials and instructions are provided in the intervention kit. In addition, the staff should copy materials, purchase incentives (described below) and other materials necessary to implement the intervention. Staff should create a culturally sensitive atmosphere and should understand the participant's cultural heritage and institutional barriers. Staff-participant language and dialect matches should also be considered. This will enable the staff to understand how the clients relate to the world.

RECRUITMENT

To encourage participation, SISTA should be publicized as a program for African-American women developed by African-American women that discusses dating, relationships, healthy sexual practices, and works at improving women's ability to effectively communicate with sexual partners. SISTA is a behavioral change intervention targeting women at very high risk for HIV. Clients may be recruited from various venues, including shelters, juvenile court systems, bars, focus groups, jails/prisons, STD clinics or community organizations. Specific cultural needs should be addressed when finding a client population.

Agencies implementing SISTA should see the Procedural Guidance for Recruitment in this document for recruitment strategy options.

Incentives can be used to effectively enhance retention in the SISTA program. For example, bus tokens may be used to provide women with transportation to and from the sessions, childcare may be provided during the sessions. In addition, gift certificates, monetary incentives, and food are all used as positive reinforcements.

PHYSICAL SETTING AND CHARACTERISTICS

Agencies implementing SISTA should choose a location that is easily accessible from public transportation routes. The intervention sessions must be conducted in a secure location such that confidentiality of participants is maintained. It is important that sessions are not interrupted by distractions, such as people entering and exiting the room, or outside noise levels. The location should be able to accommodate 10-12 persons comfortably and privately. In addition, the agency should take into consideration the intervention activities, including role play and role demonstration.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement POL the following policies and procedures should be in place to protect clients, the agency, and the facilitators:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data,

behavioral and clinical surveillance, and the state or local HIV prevention plan created with input from the state or local community planning group(s).

Informed Consent: Agencies must have a consent form which carefully and clearly explains in accessible language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Legal/Ethical Policies: Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility if a client tests positive for HIV. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Linkage of Services: Recruitment and health education and risk reduction must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, or other Health Department/Community Based Organization prevention programs) if clients need additional assistance in decreasing risk behavior.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National*

Standards for Culturally and Linguistically Appropriate Services in Health Care which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: Agencies conducting recruitment, outreach, and health education and risk reduction, must establish a code of conduct. This code should include, but not be limited to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance (QA) activities for both providers and participants should be in place when implementing SISTA.

Provider: Facilitators of SISTA should have extensive knowledge of HIV transmission and statistics in their local jurisdictions as well as national statistics. Facilitators should reflect the target population in race and gender and will be expected to deliver the information in a non-threatening and culturally relevant manner. Agencies should have in place a mechanism to ensure all sessions and core elements, as described above, are implemented. QA activities can include direct observation and review of sessions by staff involved in the intervention. The review could focus on the quality (or adherence to the fidelity) of the sessions delivered, and the responsiveness and openness of the women to the facilitator. Facilitators should collect all evaluation forms following each session and ensure participant confidentiality. In addition, facilitators should ensure that all participants are actively participating in each of the sessions. Bi-monthly meetings with supervisors to discuss progress and/or opportunities for change are encouraged.

Participants: The participants' satisfaction with the intervention and their comfort should be assessed during each session. Evaluation forms are provided in the intervention box and should be disseminated during each session. In addition, agencies can develop their own forms to assess participant satisfaction.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.A-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.
 - **I.B-** The proportion of person who access counseling and testing from each of the following interventions: individual level interventions and group level interventions.
 - **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).
 - **III.B-** Proportion of persons at very high risk for HIV infection that completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
 - **V.A -** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

¹DiClemente RJ, Wingood GM. A Randomized controlled trial of an HIV sexual risk reduction intervention for young African American women. *The Journal of the American Medical Association*, 1995, 274(16), 1271-1276.

²Wingood GJ, DiClemente RJ. Partner influences and gender-related factors associated with noncondom use among young adult African American women. *American Journal of Community Psychology*, 1998, 26(1), 29-49.

³Wingood GM, DiClemente RJ. Application of the theory of gender and power to examine HIV-related exposures, risk factors, and effective interventions for women. *Health Education & Behavior*, 2000, 27(5), pages 539-565.

The SISTA Project intervention box was developed by Sociometrics. For more information on receiving training on this intervention, please visit www.effectiveinterventions.org.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF STREET SMART

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF STREET SMART

Street Smart is an intensive HIV/AIDS and STD prevention program for youth whose behaviors place them at very high risk of becoming infected.^{1,2} Life circumstances define risk for some youth; being gay, runaway or homeless, or a sex offender increases the potential for risky behavior. Street Smart is designed for runaway and homeless youth, yet it can be easily adapted for very high risk youth in other settings. This intervention has been packaged by CDC's Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

The Street Smart program is the product of extensive collaboration among researchers, staff from public and private agencies serving homeless and runaway youth, and youth from diverse backgrounds. Staff and youth from homeless youth shelters and drop-in centers were instrumental in identifying key strategies to plan, implement, and evaluation the intervention.

Street Smart draws on social learning theory that describes the relationship between behavior change and a person's beliefs in his/her ability to change a behavior and that changing that behavior will produce a specific result. Street Smart links thoughts, feelings, and attitudes to behavior change. Beliefs about the consequences of behavior and perceptions for self-efficacy are key determinants of effective behavior change.

The Street Smart program is held in conjunction with existing services that attract youth, such as after dinner or before an art class. The intervention held over a two to six week period. The program consists of eight 1.5 to two-hour drop-in group sessions, one individual session, and a group visit to a community health resource. While it is preferable that teens attend every session, the program is designed so that each session stands on its own. Ideally six to ten youth attend the eight group sessions which are facilitated by two trained counselors. The intervention's goal is to reduce unprotected sex, number of sex partners, and substance use among runaway youth. The Street Smart program targets runaway youth, 11 – 18 years of age.

The sessions take place in small groups to provide support for a behavior change environment among the participants. A private session with a counselor is also included to allow each youth to personally identify and problem-solve their own barriers to safer sex and risk for HIV transmission. Additionally, participants can access medical care, mental health care, and referrals for specific individual health concerns if needed.

When Street Smart was implemented in research field trials, it was found that participants reported lower rates of substance use and unprotected sex acts following their participation in the

group sessions. Young women self-reported greater reductions in substance abuse and unprotected sex acts than young men; and African American youth self-reported less substance use than youth of other ethnic groups.^{1,2}

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. The Street Smart program has 4 core elements:

- 1) Increasing knowledge about HIV and its transmission including information about perinatal transmission, benefits of HIV testing and knowing one's status, stigma, and the emerging epidemiology of the epidemic.
- 2) Identifying personalized knowledge which consists of five basic components: outcome expectancies, peer and partners' social norms, self-efficacy, and perceived risk.
- 3) Acquisition of targeted skills in social assertiveness, condom use, problem-solving, self-talk, goal setting, and affect awareness and regulation.
- 4) Access to resources to effect positive change in their lives.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. Key characteristics of Street Smart are:

- Convening groups of 6 to 10 adolescents of both sexes
- Delivering the intervention in eight, 90- to 120-minute sessions, one individual counseling session, and one trip to a community resource
- Conducting the intervention sessions in a large, comfortable room protected from interruptions
- Reinforcing positive behavior through frequent use of tokens and verbal appreciation
- Building group cohesion through participants sharing and giving appreciation to others for their contributions
- Eliciting participants' assessment of their feelings by using the "Feeling Thermometer" and labeling the feelings they are experiencing
- Using role-playing as an opportunity for participants to practice and observe typical circumstances in an instructive and supportive environment
- Videotaping exercises so participants can see themselves as others see them
- Applying problem-solving steps to realistic circumstances

- Creating concern over unsafe sexual behaviors and involvement in risky situations and risky partners
- Enhancing affective and cognitive awareness, expression, and control through exercises that cover topics such as:
 - HIV/STD terms, future dreams, self-defeating thoughts, condom misconceptions, how drugs/alcohol affect actions, weighing pros & cons, coping styles, problem analysis, sexual values, self-talk, and goal setting
- Teaching HIV/AIDS risk hierarchy and its application to oneself through exercises that include:
 - HIV/STD transmission, relative safety of different sex acts, familiarization with condoms, pros & cons of getting an HIV test, and consequences of behaviors and choices
- Using peer support to train in recognizing triggers for personal risk through activities such as:
 - exploring thoughts and feelings that lead to unsafe acts, recognizing those feelings, identifying circumstances that contribute to unsafe acts, analyzing problems, and encouraging participants to give feedback on role-plays, express appreciation, and give tokens
- Building skills in problem solving, personal assertiveness, and HIV/AIDS harm reduction with exercises such as:
 - setting your own sexual limits, putting condoms on penile and vaginal models, role-playing affects of drugs/alcohol, practicing problem-solving steps, getting back in control, trying relaxation techniques, assessing a partner's risk, using "I" statements in assertive communication, switching negative thoughts to positive ones, and dealing with rationalizations and slip-ups

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the conduct of the intervention. Procedures for implementing the eight sessions of Street Smart follow below:

Getting the Language of HIV and STDs: A basic assumption in this session is that knowing the facts about HIV/AIDS is essential, because this knowledge allows a person to protect himself/herself and others. Furthermore, understanding HIV/AIDS allows people to monitor their own effectiveness at implementing HIV intervention strategies. This session uses a knowledge game and role plays so participants will become familiar with the key components of the intervention (tokens, feeling thermometer) and receive basic information/understanding of HIV and other STIs, how they are transmitted, and their personal risk factors.

Personalized Risk: The main point of this session is to use role plays and group brainstorming to help participants figure out which of their behaviors put them at risk, and which triggers lead to unsafe behaviors. In this session, participants will increase familiarity with key components of intervention, understand safer sex, recognize personal risk behaviors, learn their triggers that increase their personal risk and learn to set personal limits

How to Use Condoms: Youth often feel anxiety about condom use. The main point of this session is for participants to be comfortable talking about and using condoms. Participants will

increase familiarity with key components of intervention, learn and practice the use of male and female condoms correctly and increase comfort level with condoms.

Drugs and Alcohol: The main point of this session is to use role plays and confronting beliefs so participants can identify how drugs and alcohol affect their thinking and choices. Participants will understand how alcohol and drugs affect the ability to practice safer sex, examine the pros and cons of substance use, learn how drugs and alcohol can affect a person, understand addiction and triggers for substance use, and learn skills to break the cycle of addiction.

Recognizing and Coping with Feelings: The main point of this session is to use role plays and the feeling thermometer so participants will be able to identify different coping styles in tough situations, and to problem solve solutions. Participants will learn skills to cope with stressful feelings, become familiar with the SMART method for coping/problem-solving and learn relaxation techniques

Negotiating Effectively: Participants will learn how to stand up for their own personal values and review key components. Participants will use interpersonal problem solving and role playing to explore personal sexual values, learn to deal with peer pressure, develop problem-solving skills, and learn to communicate effectively using “I” statements.

Self Talk: Participants engage in educational games and exercises to learn how to use their thoughts and self-talk to help them make safer decisions. Participants will review key components, learn how to think through positive and negative events to facilitate protective actions, learn to break the cycle of negative thoughts, practice thinking positive thoughts about self and learn helpful ‘self-talk’ to keep themselves safe.

Safer Sex: Participants engage in a small group discussion and create a media message (music video, soap opera, commercial) to figure out why they engage in risky behaviors and to learn how to argue against their rationalizations. Participants will review key components, figure out personal risk in unclear sexual situations, learn to combat rationalizations, strategize how to deal with slip-ups and apply what they have learned for the making of a video or soap opera.

RESOURCE REQUIREMENTS

Facilitators should have extensive experience working with youth and extensive knowledge of at-risk youth. The intervention is implemented by trained counselors. Facilitators should understand the underlying principles of the program, the theories behind the intervention and have knowledge of the way that youth operate. For example, facilitators need to know that few youth know how to apply safer sex practices, and that youth is a time of experimentation, and that having been sexually abused increases the risk of youths practicing unsafe sex. The Street Smart implementation manual has guidance on other things facilitators need to know. Facilitators need to be skilled in group dynamics, relating the intervention content to the lives of the youth, to reward frequently observable positive behavior, to be supportive, non-judgmental, give praise and build on strengths. Facilitators should be aware that some participating youth may already have been adversely affected by the HIV epidemic. The Street Smart implementation manual provides other tips for successful facilitation of the intervention.

The intervention requires a private room, a VCR, television and a video camera. Staff need to know how to operate the equipment and how to teach others to use it.

Community resources must be in place to facilitate the desired behavior—practicing safer sex. From research on teenage pregnancy and drug and smoking prevention, it is known that coordinating services for youth is critical. These youth often rely heavily on peers rather than adults for obtaining information and other forms of support partly because these other sources of support are unavailable to them.

The youth served in this training program need a variety of resources, including HIV counseling testing and referral, health care, alcohol and drug rehabilitation, legal aid, advice on how to take the GED exam, help in enrolling in athletic programs, and housing. To access these services, youth also need to become more self-directed, responsible consumers. To meet this objective, youth require more than just a discussion of where these services can be obtained: they need to be taken to community agencies and centers where they can personally meet the staff and become familiar with different sites and their services.

The stabilization and integration of community social services for youth may be the single best predictor of safer sex and drug use behavior. Therefore, it is essential that HIV/AIDS prevention programs establish strong working links between difference social service agencies at both the leadership and staff levels.

RECRUITMENT

Implementing Street Smart involves recruiting very high risk youth to participate in the intervention. Staff can identify participants and present the intervention as part of the runaway and homeless shelter's best practices that benefit clients. Incentives, when possible, can play a role in recruitment. General recruitment into the eight Street Smart sessions can include word of mouth, and other marketing strategies including flyers, newsletters, and special events. Peer-to-peer recruitment strategies can also be effective ways to bring clients into the agency, and to participate in the intervention. Please see the Procedural Guidance for Recruitment in this document for explanation of possible recruitment methods.

PHYSICAL SETTING CHARACTERISTICS

Ensuring the success of Street Smart begins even before the first session. When designing an HIV/STD prevention education program, it is important that participants have an inviting, comfortable, and safe environment. The following items need to be addressed:

- Attractive and easily understood promotional materials
- Adequate notice so prospective participants can arrange their schedules to fit the program
- A telephone number for questions regarding the program
- A private room

- A room large enough for the expected number of participants
- Comfortable temperature and fresh air
- Refreshments
- Sufficient materials for all participants, such as nametags, tissues, paper, pens/pencils, copies of the agenda
- Clear, correct, and understandable visual aids
- A suggestion/comment box to permit individuals to ask questions or give comments anonymously

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement Street Smart, the following policies and procedures should be in place to protect participants, and the agency:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in accessible language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility if a client tests positive for HIV. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see

the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, or other Health Department/Community Based Organization prevention programs) if clients need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

A strong component of quality assurance is preparing a plan to implement Street Smart. Developing a comprehensive implementation plan will facilitate understanding and “buy-in” from key stakeholders and increase the likelihood the intervention runs smoothly.

Quality assurance on this intervention also requires there is someone at the agency that will provide hands-on leadership and guidance for the intervention—from preparation through institutionalization. In addition, a decision maker is needed in the agency who will provide higher-level support, including securing resources and advocating for Street Smart, from preparation to institutionalization.

The protocol used when linking youth and escorting youth to community resources also involves a measure of quality assurance in that consumers from the community resource can be paired with youth when touring the resource and its services. Ensure that community resource staff follow-up and invite youth back and provide feedback to your sponsoring program on those visits.

Throughout implementation, it is necessary to determine whether staff is delivering Street Smart with fidelity to the four core elements. A fidelity checklist is available in the intervention kit and can be used by the agency as a quality assurance tool for this purpose. It is also necessary to identify and address any issues to assure the intervention is meeting the needs of agency clients and staff.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;

- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).
 - **III.B-** Proportion of persons at very high risk for HIV infection that completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information

KEY ARTICLES AND RESOURCES

¹ Rotheram-Borus M.J, Van Rossem R, Gwadz M, Koopman C, Lee M. (1997). Reductions in HIV risk among runaway youths. Los Angeles, CA: University of California, Department of Psychiatry, Division of Social and Community Psychiatry.

² Rotheram-Borus M.J, Koopman C, Haignere C, Davies M. (1991). Reducing HIV sexual risk behaviors among runaway adolescents. *Journal of the American Medical Association* 266(9), 1237-1241.

Kelly JA, Heckman TG, Stevenson LY, et al. (2000). Transfer of Research-Based HIV Prevention Interventions to Community Service Providers: Fidelity and Adaptation. In *AIDS Education and Prevention*, 12, Supplement A, 87-98. The Guilford Press.

Moon MW, McFarland W, Kellogg T, Baxter M, Katz M, MacKellar D, Valleroy L. (2000). HIV risk behavior of runaway youth in San Francisco: Age of Onset and Relation to Sexual Orientation. *Youth and Society*, Vol. 32, No. 2, December. Sage Publications, Inc.

Rotheram-Borus M.J, Noelle, L. (2000). Training facilitators to deliver HIV manual-based interventions to families. In *Working with families in the era of HIV/AIDS*. Pequegnat W, Szapocznik J. (eds.). Sage: New York.

For more information on the Street Smart intervention, training and technical assistance, or to get your name on a list for a future training, please go to the website:

www.effectiveinterventions.org.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF MANY MEN, MANY VOICES

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF MANY MEN, MANY VOICES

Many Men, Many Voices (MMMV) is a six- or seven-session, group level HIV/STD prevention intervention for gay and bisexual men of color adapted from the Behavioral Self-Management and Assertion Skills intervention¹ (now called Partners in Prevention) developed by the Center for AIDS Intervention Research (CAIR) in the Department of Psychiatry and Behavioral Medicine at the Medical College of Wisconsin. This intervention has been packaged by CDC's Diffusion of Effective Behavioral Interventions (DEBI) project and information on obtaining the intervention training and materials is available at www.effectiveinterventions.org.

The original model intervention was condensed from twelve sessions to six (with an optional seventh) but individual sessions were expanded from 90 minutes to 2-3 hours. It was adapted and tailored using the strategies outlined in the *Procedural Guidance*, to address behavioral influencing factors specific to gay men of color including cultural/social norms, and values and sexual relationship dynamics. The adaptation, tailoring and implementation of this intervention were done in partnership with Men of Color Health Awareness (MOCHA), People of Color in Crisis (POCC) and the Center for Health and Behavioral Training (CHBT).

Many Men Many Voices is designed to be facilitated by a peer in groups of 6-12 participants. The three hour sessions aim to foster positive self identity, educate participants about their HIV/AIDS risk and teach assertiveness skills. For participants who are unaware of their HIV status, the benefits of knowledge of serostatus should be addressed, and referral for counseling and testing should be provided when appropriate. The program utilizes behavioral skills practice, group discussions, role play and lectures in highly interactive sessions.

In the original Partners in Prevention intervention, gay men who participated reduced their frequency of unprotected anal intercourse and increased their use of condoms significantly more than men in the control condition.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are

derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. There are 5 core elements of MMMV:

- 1) Educate clients about HIV risk and sensitize to personal risk.
- 2) Develop risk reduction strategies.
- 3) Train in behavioral skills.
- 4) Train in sexual assertiveness.
- 5) Provide social support and relapse prevention.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. MMMV has the following key characteristics:

- Foster positive identity development for gay men of color by exploring the dual identity culture of gay men of color, addressing social and cultural norms within racial/ethnic communities, exploring positive and negative peer influences, setting self-standards and clarifying values
- Discuss sexual roles and risks, addressing knowledge of HIV transmission risk and exploring beliefs about those risks
- Address perceived personal risk and personal susceptibility for HIV infection as well as the perceived benefits and outcomes of remaining HIV negative
- Increase skills and self-efficacy for protective behaviors and intentions to engage in those behaviors
- Explore sexual relationship dynamics including power dynamics
- Address the importance of peer support and social influence on maintaining healthy behaviors

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for implementing MMMV follow.

Many Men, Many Voices is implemented by one or two group level facilitators who are trained in the specific content of each group session. The facilitators are responsible for coordinating all activities and organizing all aspects of the intervention. At least one of the facilitators must be a gay or bisexual male of color.

The intervention consists of educational materials for distribution which may be used to recruit persons at risk into the group. Outreach by project staff is also necessary to recruit gay/bisexual men of color into the intervention sessions. The intervention was not designed for heterosexual males and they should not be included in the sessions. Men of color who have sex with other

men but do not identify as “gay” or “bisexual” are appropriate for the intervention as long as they are willing to discuss the STD and HIV risks of male to male sexual behaviors and the risk reduction methods that constitute safer sex.

The original 12 session intervention¹ was tailored and condensed into the 6 sessions of Many Men, Many Voices. An optional seventh session may be added at the discretion of the group facilitators. The seven sessions address specific influencing factors in a purposeful sequence including:

- Session 1: The Dual Identity Culture of Gay Men of Color
- Session 2: HIV Prevention for Gay Men of Color – Sexual Roles and Risks
- Session 3: HIV Risk Assessment and Prevention Options
- Session 4: Intentions to Act and Capacity to Change
- Session 5: Partner Selection, Communication and Negotiation
- Session 6: Social Support and Problem Solving to Maintain Change
- Session 7 (optional): Building a Healthy Community

The original 75-90 minute sessions were tailored and expanded to 2-3 hour Many Men, Many Voices sessions. Sessions contain very little presentation of information, and instead are highly interactive and allow for the clients to gain knowledge experientially (for example, through the use of educational games, and other exercises). Through their formative evaluation, the agencies that adapted the intervention found that the African American gay/bisexual men that they served were more inclined to attend 7 sessions of 2-3 hours each rather than 12 sessions of 75-90 minutes. An agency may conduct its own formative evaluation to determine whether participation rates would increase or decrease relative to the number of sessions and the length of each session. Whether the agency chooses to conduct fewer sessions of longer length or to conduct more sessions of shorter length should be based on client needs and client convenience. The intervention may also be condensed into a weekend retreat format, covering the 18-21 hours of intervention materials over the course of a single weekend. The entire content of the sessions constitutes the core elements of this intervention and so the entire content must be covered to implement the intervention with fidelity.

RESOURCE REQUIREMENTS

The agency should hire at least one full-time group facilitator. A second facilitator can be hired at a full- or part-time level depending on the level of need in the community. Group facilitation skills are necessary and should be a consideration in hiring staff or in initial training of staff. Facilitators are responsible for all aspects of the program including recruitment, group facilitation, record keeping, quality assurance, and monitoring and evaluation. Therefore it is recommended that each group facilitator run no more than two concurrent groups. An administrative employee of the community based organization typically supervises the group facilitator(s).

In addition to staff of the intervention, materials that are needed to conduct the intervention include markers, easel charts and newsprint, a VCR and television, an overhead projector, masking tape, poster boards, and clothespins.

RECRUITMENT

The target population for Many Men Many Voices is gay and bisexual men of color. Recruitment into the intervention sessions will include outreach to venues where MSM of color can be reached. Printed materials may also be used to recruit MSM of color into the intervention. The group facilitators generally recruit participants, but clients may also be referred to the groups through other programs. It is best if the group facilitators interview potential group members prior to the first group to determine if the individual is appropriate for the group.

Agencies wishing to implement Many Men, Many Voices should review the Procedural Guidance for Recruitment in order to choose a recruitment strategy that will work in the setting in which they plan to implement MMMV.

PHYSICAL SETTING CHARACTERISTICS

Agencies implementing Many Men Many Voices should choose a location that is easily accessible from public transportation routes and is also in communities where young gay/bisexual men of color live, work and socialize. The groups are usually held at the CBO, but can be held in other locations. Ideally the space should have comfortable seating for discussions. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room, or outside noise levels.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement MMMV the following policies and procedures should be in place to protect participants, the agency, and the MMMV program team:

Targeting of Services: Agencies must establish criteria for, and justify the selection of, the target populations. Selection of target populations must be based on epidemiological data, behavioral and clinical surveillance, and the state or local HIV prevention plan created with input from the state or local community planning group(s).

Informed Consent: Agencies must have a consent form which carefully and clearly explains in accessible language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Safety: Agency policies must exist for maintaining safety of workers and clients. Plans for dealing with medical or psychological emergencies must be documented.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Legal/Ethical Policies: Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility if a client tests positive for HIV. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Linkage of Services: Recruitment and health education and risk reduction must be linked to counseling, testing, and referral services for clients of unknown status, and to care and prevention services for people living with HIV (PLWH). Agencies must develop ways to assess whether and how frequently the referrals made by staff were completed.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, or other Health Department/Community Based Organization prevention programs) if clients need additional assistance in decreasing risk behavior.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Personnel Policies: Agencies conducting recruitment, outreach, and health education and risk reduction, must established a code of conduct. This code should include, but not be limited to, no drug or alcohol use, appropriate behavior with clients, and no loaning or borrowing of money.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and

are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance (QA) activities for both facilitators and participants should be in place when implementing MMMV:

Facilitator: Training for facilitators should address the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practice of mock intervention sessions. Agencies should have in place a mechanism to ensure that all session protocols are followed as written. QA activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on adherence to session content, use of interactive techniques; accessibility and responsiveness to expressed participant needs; and important process elements (e.g., time allocation, clarity of presentation). Selected intervention record reviews should focus on assuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at the final session of each module. Process monitoring systems should also track the number of sessions each participant attends, as well as reasons for non-attendance.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements;
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements;
- Collect and report data consistent with the CDC requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **I.A-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.
 - **I.B-** The proportion of person who access counseling and testing from each of the following interventions: individual level interventions and group level interventions.

- **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).
- **III.B-** Proportion of persons at very high risk for HIV infection that completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
- **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
- **V.A -** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

¹Kelly JA, St. Lawrence JS, Hood HV, Brasfield TL. (1989). Behavioral intervention to reduce AIDS risk activities. *Journal of Consulting and Clinical Psychology*, 57(1), pp. 60-67.

Section 3, Part C: Partner Counseling and Referral Services (PCRS)

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF PARTNER COUNSELING AND REFERRAL SERVICES

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF PARTNER COUNSELING AND REFERRAL SERVICES

Evidence suggests that most new HIV infections originate from HIV-infected persons not yet aware of their infection.¹ This finding emphasizes the need to identify HIV-infected persons and link them to medical, prevention, and other services as soon as possible after they become infected. One strategy for accomplishing this is voluntary partner counseling and referral services (PCRS), including partner notification.^{2,3,4} In most jurisdictions, state and/or local health departments are legally responsible for ensuring the public health through the control of infectious diseases. PCRS is a strategy that most health departments use to achieve this goal. For this reason, CBOs who wish to provide PCRS are required to collaborate with their state and/or local health departments.

PCRS is one of a number of public health strategies to control and prevent the spread of HIV and STDs. PCRS assists HIV-infected persons with notifying their partners of exposure to HIV. A key element of PCRS is informing current and past partners that a person who is HIV-infected has identified them as a sex or injection-drug-paraphernalia-sharing partner and advising them to have HIV counseling and testing. Notified partners, who may not have suspected their risk, can then choose whether to be tested for HIV. Those who choose to be tested and are found to be HIV positive can receive early medical evaluation, treatment, and prevention services, including risk reduction counseling and PCRS. Sex and injection-drug-paraphernalia-sharing partners might already be HIV-infected but be unaware of or deny their risks or their HIV status. PCRS provides an opportunity for HIV primary prevention interventions for those partners not infected with HIV and an opportunity for primary and secondary prevention for those partners living with HIV. Informing partners of their exposure to HIV is *confidential*; partners are not told who reported their name or when the reported exposure occurred. As well, information about partners is not reported back to the original HIV-infected person. It is *voluntary*; the infected person decides which names, if any, to reveal to the interviewer.

PCRS can be an effective tool for reaching persons at very high risk for HIV infection: in studies of HIV PCRS, 8%-39% of partners tested were found to have previously undiagnosed HIV infection.⁵ However, a recent survey of health departments in U.S. areas with high reported rates of HIV found that, in areas with mandatory HIV reporting, only 52% of persons infected with HIV were interviewed for PCRS.⁶ Acceptability of PCRS has been indicated in surveys of individuals seeking HIV testing, HIV-infected persons, and notified partners.^{7,8,9} PCRS has been found to be cost-effective.^{10,11,12}

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. PCRS has 6 core elements which include:

- 1) All services are both voluntary and confidential.
- 2) Identifying and contacting all persons with HIV (index or original clients) to offer them PCRS. These may be persons with newly diagnosed HIV or persons with previously diagnosed HIV who have ongoing risky sexual and injection-drug-use behaviors.
- 3) Interviewing index clients who accept PCRS to elicit names of and locating information for sex and injection-drug-paraphernalia-sharing partners.
- 4) Locating named partners, notifying them of their exposure to HIV, providing HIV prevention counseling to them, and recommending HIV testing.
- 5) Providing HIV counseling and testing to partners and ensuring they receive their test results.
- 6) Linking partners, especially those who test positive, to appropriate medical evaluation, treatment, prevention, and other services.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. PCRS has 4 key characteristics:

- May be delivered through provider-referral, whereby the PCRS worker locates and informs sex or injection-drug-paraphernalia-sharing partners of their exposure; and/or through client-referral, whereby the infected person takes responsibility for informing his or her partners. Sometimes a combination of these approaches – either contract-referral or dual-referral (see p.65 for definitions) – is used. Provider referral has been shown to be more effective than client referral.
- Is delivered in a continuum of care that includes the capacity to refer or test sex and injection-drug-paraphernalia-sharing partners to HIV counseling, testing, and treatment, as well as to other services (e.g., STD treatment, family planning, violence prevention, drug treatment, social support, housing).
- May reduce behavioral risks for acquiring or transmitting HIV infection by providing client-centered counseling for HIV-infected individuals and their partners. In addition, client-centered counseling will help the provider understand the readiness of the client to

notify partners. This will allow the provider to offer services to assist the client in successfully notifying partners without adverse consequence.

- Should not be a one-time service. It should be offered as soon as an HIV-infected individual learns his or her serostatus and made available throughout that person's counseling and treatment. If new partners are exposed in the future, PCRS should be made available again. HIV-infected individuals should have the ability to access PCRS whenever needed.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for PCRS follow.

PCRS activities are science-based and require knowledge, skills, and training. It is part of a complex array of services needed by PLWH, which begins when a person tests HIV-positive and continues after the client enters care.

PCRS is usually done by health departments; therefore, a community-based organization (CBO) planning to provide any or all services of PCRS should collaborate closely with its state or local health department to avoid duplication of services and ensure that all CBO procedures are consistent with health department policies and procedures. A written agreement with the state or local health department outlining the roles and responsibilities of the CBO and the health department should be in place before a CBO implements PCRS. **In some jurisdictions, state or local laws and regulations limit or prohibit PCRS being done outside the health department.**

PCRS is not complete without each of its 6 core elements. Therefore, CBOs planning to provide PCRS must either fully address all elements, or, if this is not possible, maintain formal written agreements with other agencies, organizations, or providers that will deliver the other elements. In addition, because most HIV diagnoses are made by private medical providers, CBOs should consider working with private providers as well as with other agencies and organizations involved in the care of PLWH to improve understanding of the value of PCRS and to integrate PCRS into their other services. At a minimum, CBOs providing PCRS should ensure that information about their services is easily accessible by health care providers in the public and private sectors and other agencies and organizations diagnosing or providing services to PLWH.

Two major sources of recruitment for PCRS include health care providers who report HIV cases to the health department according to state regulations and counseling, testing, and referral sites. Agencies can assist with referral into PCRS by helping health care providers understand the benefits to PCRS and by ensuring that all positive HIV test result counseling sessions at counseling and testing sites include referral to PCRS.

Interviewing index clients who accept PCRS serves several functions including, providing client-centered HIV prevention counseling and information to the index client, assessing the index client's need for other services and making appropriate referrals, and eliciting names of and locating information on sex and injection-drug-paraphernalia-sharing partners or children or infants who may have been exposed perinatally or through breast feeding. During the interview, the PCRS provider should also establish a plan for notifying partners (see below for notification

strategies) and if appropriate arranging for follow-up to determine if contact was made. PCRS should be an ongoing process for clients who have new sex or injection-drug-paraphernalia-sharing partners; therefore, clients who remain sexually active or continue to use injection drugs should be counseled regarding self-disclosure of HIV status and provided opportunities to develop their disclosure skills.

PCRS programs should have explicit procedures regarding partner elicitation, including, but not limited to:

- Determining the interview period (i.e., how long before the index client's diagnosis to attempt to identify partners)
- Following special considerations related to spouses (e.g., federal legislation and related state laws and regulations requiring that a good-faith effort be made in notifying spouses), including establishing an approach to clients who will not give consent and will not allow the provider to notify current or past marriage partner(s)
- Establishing an approach to clients who decline to disclose partner names
- Explaining to index clients all available options for notifying their partners (e.g., client-, provider-, contract-, or dual-referral), including advantages and disadvantages of each
- Assessing and addressing potential for partner violence. PCRS workers should be aware of the potential for partner violence and be prepared to make appropriate referrals. If the provider has an indication of a potentially violent situation for the client or others, the provider must make an assessment prior to notifying the partner, seek expert consultation before proceeding, and comply with relevant state laws and local regulations
- Formulating plans for notifying partners of their exposure including if, how, and when specific partners will be informed of their risk of exposure

Locating and notifying named partners should begin as soon as possible after the diagnosis of HIV in the index patient. Partners should be informed of their possible exposure to HIV; provided with accurate information about transmission and prevention of HIV; informed of the benefit of knowing one's status; assisted in accessing counseling, testing, and referral services; and cautioned about the possible negative consequences of disclosure of one's own or another's HIV status.

There are three main strategies for reaching and informing partners of their exposure. PCRS workers should assist clients in determining the best strategy for notifying each partner named.

- **Provider-Referral** – the clinical care provider, health department staff, or other PCRS provider, with permission from the HIV-infected client, informs the partner(s) and refers him or her to counseling, testing, and other support services. Although some clinicians may wish to take on the responsibility for informing partners, one observational study suggested that health department specialists were more successful than physicians in interviewing patients and locating partners.¹³
- **Patient- or Client-Referral** – the HIV-infected person accepts full responsibility for informing his or her partners of their possible exposure to HIV and for referring them to HIV counseling and testing services. Clients should receive information and coaching regarding the best way to inform their partners, dealing with the psychological and social

impact of HIV status disclosure, dealing with partner reactions (including violence), and on how and where partners can access counseling and testing. Although some persons initially prefer to inform their partners themselves, many clients often find this more difficult than anticipated. Furthermore, results from a randomized trial showed that notification by health department staff was substantially more effective than notification by the infected person.¹⁴

- **Combined Referral** – two strategies of combined referral provide variations on provider- and client-referral strategies by including elements of both.
 - *Contract-referral*, the infected person has a specified number of days to notify his or her partners. If, by the contract date, the partners have not come for counseling and testing, they are contacted by the PCRS provider.
 - *Dual-referral*, the HIV-infected client and the provider inform the partner together. Some reports of partner violence after notification suggest a need for caution, but violence seems to be rare.^{15,16}

Many states and some cities or localities have laws and regulations about informing partners of their exposure to HIV. Some health departments require that even if a client declines to report a partner, the PCRS provider must report to the health department any partner of whom he or she is aware. Some states also have laws requiring disclosure by providers to third parties known to be at significant risk for future HIV transmission from clients known to be infected. This is called duty to warn.¹⁷ Agencies or organizations that choose to implement PCRS should familiarize themselves with local, state, and federal regulations governing informing partners of potential exposure as well as potential duty to warn. Finally, the Ryan White CARE Reauthorization Act requires that health departments receiving Ryan White funds show good faith efforts to notify marriage partners of HIV-infected persons.

All partners notified should receive appropriate client-centered counseling and be offered anonymous or confidential testing (if not already known to be positive) and referral services. Testing may be done at the time of notification (rapid testing (RT) and non-blood specimen collection options can facilitate this type of testing) or may be accomplished by escorting or referring the partner to a counseling and testing site. For partners who choose non-RT methods, detailed locating information should be obtained to ensure that results are given, and for those partners referred, follow-up should be arranged to ensure that counseling and testing were provided. Regardless of how testing is accomplished, all aspects of counseling and testing should follow CDC's guidelines¹⁸ and must be in accordance with federal, state, and local laws, regulations, and policies, including the Clinical Laboratory Improvement Amendment (CLIA). PCRS workers should also maintain referral agreements and up-to-date resource guides to provide appropriate referrals. For partners who test positive, linking them to appropriate medical care and prevention services is essential. For partners who are HIV-negative referrals for prevention services should be made.

Because PCRS may place a substantial burden on resources, CBO program managers may need to develop policies for prioritizing PCRS activities, such as the order in which PLWH are offered PCRS or the order in which partners are located and offered counseling, testing and referral and PCRS. The PCRS Guidance¹⁸ suggests the following be considered when prioritizing efforts:

- The partner who is most likely to transmit HIV to others should receive the highest priority.
- Partners of a recently infected client who had contact in the prior 6 months are most likely to have been exposed and should be considered high priority.
- Partners who are unlikely to be aware of their exposure to HIV should be considered high priority.
- Current partners are considered a high priority because they may be at continued risk for infection.
- Partners with a history of other STDs are high priority.
- Partners of clients with resistant strains of HIV should be considered high priority.

RESOURCE REQUIREMENTS

PCRS services include three phases: working the HIV infected client, locating partners, and notifying partners of their potential exposure and providing additional services. These may all be performed by the same person within an agency, or may be divided between two or more individuals depending on the needs of the agency and the skill level of the staff. If an agency provides CTR services, elicitation may be included within counseling for clients who test positive for HIV, although agencies should be aware that including elicitation within the counseling session will increase significantly the amount of time required for counseling. This service may also be conducted at a later time if the client is not ready to provide this information immediately or if elicitation of partners does not fit within the logistics of the CTR service, however, the success of PCRS as a prevention strategy may be diminished if newly diagnosed clients are lost to follow up at a later time. Locating and notifying partners may require a greater time commitment from the PCRS worker depending on the number of partners elicited, the extent and accuracy of the locating information provided, whether counseling and testing will be provided on site, and on the type of referrals that the client wishes to pursue. Finally, accurate records must be maintained to ensure that all clients are reached and partners are notified and provided with appropriate referrals for CTR (or are provided CTR if the agency providing PCRS is equipped to offer this service) or other services as needed and that services are coordinated with the state or local health department. Staffing levels for PCRS will vary according to the design of the program (all workers performing all components versus division of the components between workers) and the number of clients expected to be served. In general, agencies could expect to serve up to 5-7 new clients per week for each 1.0 full-time equivalent (FTE) PCRS provider on staff. In addition, a 1.0 FTE supervisor (per 5-7 PCRS providers) will be required to oversee staff, maintain records, and work with the state or local health department to coordinate delivery of services.

RECRUITMENT

CBOs planning to provide PCRS should have clearly defined strategies for *identifying* potential index clients. All persons with newly diagnosed HIV are candidates for PCRS. Some examples of other persons who are candidates for PCRS include: HIV-infected persons who in the past were not offered PCRS, persons with previously diagnosed HIV infection who are now seeking

STD or family planning services, and persons who in the past declined or only partially participated in PCRS but have now decided to participate fully. Potential index clients may be identified from among persons already served by the CBO or may be identified by other agencies, organizations, or providers and referred to the CBO for PCRS. CBOs accepting referrals for PCRS from other agencies, organizations, or providers should do so only under a formal, written agreement (e.g., memorandum of agreement, contract) that clearly describes the roles and responsibilities of each party. Such agreements should be reviewed and approved by the health department and should ensure that appropriate consents for release of information have been signed by the referred client to allow exchange of necessary information between the CBO and the referring entity.

CBOs providing PCRS should have explicit procedures regarding contacting potential index clients and offering them PCRS, including, but not limited to, the following:

- How to contact them (e.g., in person, by telephone, by mail)
- What steps to take before contacting them (e.g., for persons with newly diagnosed HIV, ensuring that the diagnosing person or organization knows of, and agrees with, the CBO's plan to contact their client for PCRS)
- When to contact them (i.e., the intervals between identifying the client, initiating contact, and establishing contact)
- What to do and say when contacting them
- What to do if unable to locate them or if they decline PCRS when it is offered (e.g., notifying the health department of the situation)

Index clients should be offered PCRS at the earliest possible opportunity. However, for persons newly diagnosed with HIV, reactions to learning they are infected will vary and personal circumstances will differ. PCRS workers should recognize and accommodate clients who need to resolve other issues before being ready to participate in PCRS. CBOs providing PCRS should have clear guidelines for these situations to avoid inappropriate delays.

Agencies or organizations wishing to provide PCRS should review the Procedural Guidance for Recruitment (see p. 7) to determine if there are any additional recruitment strategies which might be appropriate for their target population.

PHYSICAL SETTING CHARACTERISTICS

The CBO's office or clinic provides the safest and most convenient setting in which to interview and counsel clients. This setting allows for greater control over the interview process and permits access to additional personnel and materials, including medical records. However, interviews conducted outside the office or clinic setting, in surroundings in which clients feel more comfortable, may facilitate the process. Interviews conducted in the home, for example, may afford the client ready access to information (e.g., personal address books, pictures) that can be helpful in locating partners. Interviews undertaken outside the clinic or office setting (e.g., crack houses, bars, housing projects, cars) introduce the issue of personal safety for staff, which must be taken into consideration. Regardless of where PCRS is done, confidentiality and privacy must be ensured.

When efforts to meet with a client in person have been unsuccessful or when the client is not in the same city as the PCRS worker, a telephone interview may be considered, if consistent with local policy. Telephone interviews do not allow client observation and should be used with discretion and in accordance with CDC's guidelines¹⁸ and state and local policies and procedures. When interviewing by phone, certain privacy issues must be taken into account (e.g., making sure one is speaking to the client, cellular phones are not being used, no one else is on the line).

Notification of partners should take place at the time and place that is most convenient to the partner while still assuring confidentiality of the partner being notified. In-person notification should be used wherever possible. Notification by mail may be acceptable in certain circumstances, but should always be followed by personal contact. If an agency is providing rapid testing with its PCRS services, the location should take into account the demands of this situation. Outside referrals for counseling and testing should be made in accordance with appropriate referral policies and followed up to ensure that the referral was completed.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to deliver Partner Counseling and Referral Services, the following policies and procedures should be in place to protect participants, the agency, and the PCRS provider:

Confidential and Voluntary: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained. In addition, persons testing anonymously must not be required to disclose their identity in order to receive PCRS. Finally, participation in PCRS is always voluntary, and PCRS providers should ensure that clients are aware of their right to refuse or delay their participation in PCRS.

Informed Consent: All clients tested at CDC-funded testing sites should be informed of the availability of PCRS services at the earliest opportunity. Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights as well as options for serving partners. Individual state laws apply to consent procedures for minors, but at a minimum, consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. For anonymous clients a signature is not required, but documentation that client rights were explained must be maintained in client records.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and

implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Legal/Ethical Policies: It is important to keep in mind that PCRS is an intervention that deals with disclosure of HIV status, and PCRS workers must review with the client the legal and ethical reasons for informing partners. With that in mind, agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty to warn and the agency's responsibility, especially in the case of a spouse. PCRS workers should help the HIV-positive client to prioritize partners to be notified based on the likelihood of past or future transmission. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Referrals: Agencies must be prepared to supply appropriate referrals to clients and partners, as necessary. Providers must know about referral sources for care, counseling and testing, and prevention interventions (Prevention Case Management, Health Department/Community-based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

QUALITY ASSURANCE

Training is critical for successful PCRS. Training for PCRS workers is provided by CDC and includes:

- 1) Initial training plus periodic updates on standards, objectives, and specific guidelines for PCRS.
- 2) Knowledge of HIV infection, transmission, and treatment.
- 3) Cultural competence in eliciting information on partners.
- 4) Client-centered counseling.
- 5) Protecting individuals' rights to privacy.
- 6) How to use scientific information in prioritizing partners.
- 7) How to administer HIV tests when appropriate.

- 8) How to defuse potentially violent situations involving clients, partners, or staff.
- 9) Understanding local, state, and federal laws regarding PCRS as well as health care issues including the right to privacy and confidentiality.

Quality assurance methods including written job descriptions, periodic direct observation of PCRS workers, peer review of selected cases, and consumer satisfaction surveys should be in place to ensure that appropriate standardized methods are used for:

- 1) Counseling HIV-infected clients regarding the notification of their partners.
- 2) Developing a PCRS plan with HIV-infected clients.
- 3) Prioritizing which partners are to be reached.
- 4) Locating and informing those partners of their possible exposure to HIV.
- 5) Providing immediate counseling and testing services to informed partners and/or referring them to other service providers.
- 6) Collecting, analyzing, using, and storing PCRS data.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **III.D-** Percent of contacts with unknown or negative serostatus receiving an HIV test after PCRS notification.
 - **III.E-** Percent of contacts with a newly identified, confirmed HIV-positive test among contacts who are tested.
 - **III.F-** Percent of contacts with a known, confirmed HIV-positive test among all contacts.

- **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information
- **V.A** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

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U.S. Department of Health and Humans Services, OPHS Office of Minority Health. (2001). National Standards for Culturally and Linguistically Appropriate Services in Health Care.

National Network of STD/HIV Prevention Training Centers. <http://depts.washington.edu/nnpct/> State or local health department HIV/AIDS prevention programs. State AIDS Directors and contact information from the National Alliance of State and Territorial AIDS Directors (NASTAD). <http://www.nastad.org>